

# **EXHIBIT D**

Duane Priddy, Ph.D.

Page 1

UNITED STATES DISTRICT COURT  
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA  
CHARLESTON DIVISION

IN RE: ETHICON, INC., PELVIC )

REPAIR SYSTEM PRODUCTS ) Master File No.  
LIABILITY LITIGATION ) 2:12-MD-02327  
THIS DOCUMENT RELATES TO THE ) MDL 2327  
FOLLOWING CASES IN WAVE 1 OF ) JOSEPH R. GOODWIN  
OF MDL 200: ) U.S. DISTRICT JUDGE  
-----)  
HARRIET BEACH )  
v. ) CIVIL ACTION FILE  
 ) No. 2:12-CV-00476  
ETHICON, INC., et al. )  
-----)  
SHARON BOGGS, et al. )  
 ) CIVIL ACTION FILE  
v. ) No. 2:12-CV-00368  
 )  
ETHICON, INC., et al. )  
-----)  
JUDITH BRUHN, et al. )  
 ) CIVIL ACTION FILE  
v. ) No. 2:12-CV-00888  
 )  
ETHICON, INC., et al. )  
-----)  
JANICE COLONNA )  
 ) CIVIL ACTION FILE  
v. ) No. 2:12-CV-01274  
 )  
ETHICON, INC., et al. )  
-----)  
MARY F. CONE )  
 ) CIVIL ACTION FILE  
v. ) No. 2:12-CV-00261  
 )  
ETHICON, INC., et al. )  
-----)  
SANDRA CYRUS ) CIVIL ACTION FILE  
v. ) No. 2:12-CV-01283  
ETHICON, INC., et al. )  
-----)

Videotaped Deposition of DUANE PRIDDY, PH.D.  
March 8, 2016

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13	Videotaped Deposition of DUANE		
14	PRIDDY, PH.D., taken on behalf of the		
15	Defendants, pursuant to the stipulations		
16	agreed to herein, before Maxyne Bursky,		
17	Registered Professional Reporter, at 111		
18	Perimeter Center West, Atlanta, Georgia,		
19	on the 8th day of March, 2016, commencing		
20	at the hour of 9:59 a.m.		
21			
22			
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24			
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<p>1 APPEARANCES OF COUNSEL: 2 On behalf of the Plaintiffs: 3 EDWARD A. WALLACE, Esq. 4 TIMOTHY E. JACKSON, Esq. 5 Wexler Wallace LLP 6 55 West Monroe Street 7 Suite 3300 8 Chicago, Illinois 60603 9 312.346.2222 10 312.346.0022 (facsimile) 11 eaw@wexlerwallace.com 12 tej@wexlerwallace.com 13 FIDELMA L. FITZPATRICK, Esq. 14 Motley Rice LLC 15 321 South Main Street 16 Providence, Rhode Island 02903 17 401.457.7728 18 401.457.7708 (facsimile) 19 ffitzpatrick@motleyrice.com 20 On behalf of the Defendants: 21 CHAD R. HUTCHINSON, Esq. 22 Butler Snow, LLP 23 Suite 1400 24 1020 Highland Colony Parkway Post Office Box 6010 Ridgeland, Mississippi 39158-6010 601.948.5711 601.985.4500 (facsimile) chad.hutchinson@butlersnow.com Also Present: PHILIP KIMBALL, Videographer - - -</p>	<p>Page 6</p> <p>1 MS. FITZPATRICK: Fidelma 2 Fitzpatrick on behalf of the plaintiffs. 3 THE VIDEOGRAPHER: The court 4 reporter is Maxyne Bursky and will now 5 swear in the witness. 6 DUANE PRIDDY, 7 having been first duly sworn, testifies as follows: 8 EXAMINATION 9 BY MR. HUTCHINSON: 10 Q. Good morning, Dr. Priddy. How are you? 11 A. I'm doing well. 12 Q. Good. My name is Chad Hutchinson. I'm 13 counsel for Ethicon and Johnson &amp; Johnson. Do you 14 understand you are under oath? 15 A. I do. 16 Q. Do you understand you are giving testimony 17 subject to the penalty of perjury? 18 A. Yes. 19 Q. What is your specialty? 20 A. Polymer chemistry, materials science. 21 Q. Do you have any subspecialty? 22 A. No. 23 (Priddy Deposition Exhibit 1 was 24 marked for identification.)</p>
<p>1 (The signature of the witness to the 2 deposition was reserved.) 3 THE VIDEOGRAPHER: We are now on the 4 record. My name is Philip Kimball. I'm 5 a videographer for Golkow Technologies. 6 Today's date is March 8, 2016, the time 7 is 9:59 a.m. This video deposition is 8 being held in Atlanta, Georgia, in the 9 matter of Harriet Beach versus Ethicon, 10 Incorporated, et al., Case Number 11 2:12-CV-00476. 12 This case is being heard in the 13 United States District Court, Southern 14 District of West Virginia at Charleston. 15 The deponent is Duane Priddy. 16 Counsel, will you please identify 17 yourselves for the record. 18 MR. HUTCHINSON: Chad Hutchinson, 19 counsel for Ethicon and Johnson &amp; 20 Johnson. 21 MR. JACKSON: Tim Jackson on behalf 22 of the plaintiffs. 23 MR. WALLACE: Ed Wallace on behalf 24 of the plaintiffs.</p>	<p>Page 7</p> <p>1 BY MR. HUTCHINSON: 2 Q. I have handed you what we will mark as 3 Exhibit 1 to your deposition. Did you bring some 4 documents responsive to that notice? 5 (Witness reviewing document.) 6 A. I read through this and I believe the 7 documents provided to you are responsive, yes. 8 (Priddy Deposition Exhibit 2 was 9 marked for identification.) 10 BY MR. HUTCHINSON: 11 Q. You have handed me a flash drive that 12 we'll mark as Exhibit 2. 13 MR. HUTCHINSON: And, Counsel, I will 14 just retain, since this is my copy, we're 15 going to mark it Exhibit 2, but I'll just 16 retain control over it; is that fair? 17 MR. JACKSON: That's fine. 18 BY MR. HUTCHINSON: 19 Q. What is included on the flash drive that 20 your counsel handed me? 21 A. A copy of my report, some documents that I 22 have reviewed, my billing record, my time log in 23 this matter. That's all I recall offhand. 24 Q. Does the flash drive contain all of the</p>

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<p style="text-align: right;">Page 10</p> <p>1 documents that you reviewed and relied upon in 2 reaching your opinions?</p> <p>3 A. I believe so.</p> <p>4 Q. Have you reviewed this flash drive that 5 your lawyer has handed me?</p> <p>6 A. Yes.</p> <p>7 Q. Have you been deposed as an expert in the 8 AMS litigation?</p> <p>9 A. Yes.</p> <p>10 Q. Was that the mesh litigation?</p> <p>11 A. Yes.</p> <p>12 Q. Were you an expert, a polymer science 13 expert in that litigation?</p> <p>14 MR. JACKSON: Objection, form.</p> <p>15 A. Yes.</p> <p>16 BY MR. HUTCHINSON:</p> <p>17 Q. How many times have you been deposed in 18 the AMS litigation?</p> <p>19 A. Once.</p> <p>20 Q. Have you read your testimony transcript?</p> <p>21 A. No.</p> <p>22 Q. When were you first contacted in this 23 case?</p> <p>24 A. I'd say last September maybe.</p>	<p style="text-align: right;">Page 12</p> <p>1 the mesh degrades with oxidation?</p> <p>2 MR. JACKSON: Objection, form.</p> <p>3 A. I believe so.</p> <p>4 (Priddy Deposition Exhibit 3 was 5 marked for identification.)</p> <p>6 BY MR. HUTCHINSON:</p> <p>7 Q. Doctor, I will hand you what we'll mark as 8 Exhibit 3 to your deposition. Do you recognize that 9 as the report that you submitted in this case?</p> <p>10 (Witness reviewing document.)</p> <p>11 A. Yes.</p> <p>12 Q. Is it complete and accurate?</p> <p>13 MR. JACKSON: Counsel, I just want 14 to note on the record that there are two 15 emails at the end of this document which 16 are not part of Dr. Priddy's report.</p> <p>17 BY MR. HUTCHINSON:</p> <p>18 Q. Doctor, is that complete and accurate?</p> <p>19 A. It looks, yes, it looks like I might have 20 to update my list of scientific articles and 21 publications, but other than that, it's accurate.</p> <p>22 Q. Are you talking about you need to update 23 your CV in there?</p> <p>24 A. Yes.</p>
<p style="text-align: right;">Page 11</p> <p>1 Q. Of 2015?</p> <p>2 A. Yes.</p> <p>3 Q. Who contacted you?</p> <p>4 A. Mr. Wallace.</p> <p>5 Q. What did he ask you to do?</p> <p>6 MR. JACKSON: Objection, form.</p> <p>7 A. Serve as an expert witness in the Ethicon 8 mesh matter.</p> <p>9 BY MR. HUTCHINSON:</p> <p>10 Q. Anything else specifically that he asked 11 you to do?</p> <p>12 A. No.</p> <p>13 Q. Have you ever had any contacts with Mr. 14 Wallace before?</p> <p>15 A. Yes.</p> <p>16 Q. In the AMS litigation?</p> <p>17 A. Correct.</p> <p>18 Q. Did you reach opinions similar in the AMS 19 litigation as you have in this litigation?</p> <p>20 MR. JACKSON: Objection.</p> <p>21 A. I did not review my AMS testimony, so I 22 don't recall.</p> <p>23 BY MR. HUTCHINSON:</p> <p>24 Q. Did you opine in the AMS litigation that</p>	<p style="text-align: right;">Page 13</p> <p>1 Q. Otherwise, that report is complete and 2 accurate; is that fair?</p> <p>3 A. Yes.</p> <p>4 Q. Did anybody else work on that report other 5 than you?</p> <p>6 A. No.</p> <p>7 Q. How much time did you spend preparing that 8 report?</p> <p>9 A. Maybe twelve hours. I'm not sure.</p> <p>10 Q. Would the time that you spent preparing 11 that report be reflected on the flash drive that you 12 handed me before the deposition?</p> <p>13 A. Probably not completely because normally I 14 under-record the time I actually spend. I actually 15 generally spend more than what I write down.</p> <p>16 Q. Why do you under-record your time?</p> <p>17 A. Just because I -- I just like to make sure 18 that I'm not overcharging, so I tend to be 19 conservative when I'm recording my time.</p> <p>20 Q. Doctor, are all the opinions that you 21 intend to offer in this case included in your expert 22 report?</p> <p>23 A. I may end up doing a supplemental report.</p> <p>24 Q. But as we sit here right now, are all the</p>

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<p style="text-align: right;">Page 14</p> <p>1 opinions that you have so far included within your 2 expert report marked as Exhibit 3?</p> <p>3 A. Yes.</p> <p>4 Q. Do you have plans sitting here now to do a 5 supplemental report?</p> <p>6 A. Not specifically, but I may.</p> <p>7 Q. Why are you considering doing a 8 supplemental report?</p> <p>9 A. While I was preparing for my deposition, 10 reading through everything, I just thought it might 11 be wise for me to do a supplemental report in the 12 future.</p> <p>13 Q. On what specific issue would you do a 14 supplemental report on, sir?</p> <p>15 MR. JACKSON: Objection, form.</p> <p>16 A. I'm not sure at this point. Maybe my 17 review of the results in the 80s of Ethicon's 18 research, some things caught my eye that I thought 19 were important and I might generate some opinions 20 about those in the future.</p> <p>21 BY MR. HUTCHINSON:</p> <p>22 Q. But sitting here today, if you do a 23 supplemental report, it is your plan to do a 24 supplemental report only on the 1980 documents from</p>	<p style="text-align: right;">Page 16</p> <p>1 polypropylene?</p> <p>2 A. Not that I recall.</p> <p>3 Q. Doctor, have you ever given any 4 presentations on mesh, Prolene, or polypropylene?</p> <p>5 A. No.</p> <p>6 Q. Have you ever worked for a medical device 7 company before?</p> <p>8 A. Yes.</p> <p>9 Q. Did your work focus on mesh or 10 polypropylene?</p> <p>11 A. No.</p> <p>12 Q. Other than the attorneys here, have you 13 ever discussed your opinions with anybody else?</p> <p>14 MR. JACKSON: Objection, form.</p> <p>15 A. Are you talking about the opinions in this 16 report?</p> <p>17 BY MR. HUTCHINSON:</p> <p>18 Q. Yes.</p> <p>19 A. No.</p> <p>20 Q. Is it fair to say you have never discussed 21 your opinions with any type of scientist or medical 22 doctor or engineer; is that fair?</p> <p>23 A. That is correct.</p> <p>24 Q. Never communicated your opinions to FDA,</p>
<p style="text-align: right;">Page 15</p> <p>1 Ethicon; is that fair?</p> <p>2 MR. JACKSON: Objection, form.</p> <p>3 A. At this point, that's -- yeah.</p> <p>4 BY MR. HUTCHINSON:</p> <p>5 Q. Your reliance list, Doctor, included in 6 your expert report, is it complete and accurate?</p> <p>7 A. I believe so, yes.</p> <p>8 Q. Your CV that's included in your expert 9 report, is that the most recent version if you added 10 the publications that you referenced earlier?</p> <p>11 A. Yes.</p> <p>12 Q. What publications would you need to add to 13 your CV to make it current?</p> <p>14 A. I published a paper -- well, it was just 15 accepted by the peer reviewers -- that I am going 16 to present at a conference here in May, and I'll 17 add that.</p> <p>18 Q. What did you present about?</p> <p>19 A. It was understanding the science behind 20 the failure of exercise balls.</p> <p>21 Q. Doctor, have you ever published anything 22 regarding mesh or Prolene?</p> <p>23 A. No.</p> <p>24 Q. Have you ever published anything regarding</p>	<p style="text-align: right;">Page 17</p> <p>1 correct?</p> <p>2 A. That's correct.</p> <p>3 Q. Or any scientific organization?</p> <p>4 MR. JACKSON: Objection, form.</p> <p>5 A. That's correct.</p> <p>6 BY MR. HUTCHINSON:</p> <p>7 Q. Doctor, how many hours did you spend 8 reviewing the internal Ethicon documents?</p> <p>9 A. I would say probably 14, 15 hours.</p> <p>10 Q. Did you sign a confidentiality agreement 11 with respect to the documents you received from 12 Ethicon?</p> <p>13 A. Well, I mean, as part of my retainer 14 agreement there's confidentiality in there that I'm 15 not going to share or publish or discuss.</p> <p>16 Q. I understand. Is that retainer agreement 17 included on Exhibit 2 which is the flash drive that 18 was handed to me before the deposition?</p> <p>19 A. I'm not sure.</p> <p>20 Q. Where is the retainer agreement?</p> <p>21 A. I would have a copy probably on my 22 computer, or if not, a hard copy in my files.</p> <p>23 Q. When is the last time you have seen the 24 retainer agreement?</p>

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<p style="text-align: right;">Page 18</p> <p>1 A. I don't recall.      2 Q. Any reason to believe that it's been lost      3 or destroyed?      4 A. No.      5 Q. Other than your retainer agreement,      6 though, did you sign any type of paper regarding a      7 confidentiality agreement with respect to the      8 Ethicon documents you reviewed?      9 A. I don't believe so.      10 Q. Do you advertise your services?      11 A. Yes.      12 Q. On the internet?      13 A. Yes.      14 Q. Anywhere else?      15 A. Yes.      16 Q. Where?      17 A. I'm listed as an expert on three or four      18 different websites, I believe, that aren't mine.      19 Q. Other than the internet, do you advertise      20 your services anywhere?      21 A. No.      22 Q. Your billing rate is \$375 an hour for      23 record review and 550 for testimony?      24 A. Correct.</p>	<p style="text-align: right;">Page 20</p> <p>1 MR. JACKSON: Objection, calls for a      2 legal conclusion.      3 A. Let's put it this way: I don't advertise      4 myself as an expert for FDA.      5 BY MR. HUTCHINSON:      6 Q. Is there anything on your CV that reflects      7 your expertise as a regulatory or FDA expert?      8 A. No.      9 Q. Doctor, you are not a pathologist?      10 A. I am not a pathologist.      11 Q. Not a medical doctor?      12 A. I am not a medical doctor.      13 Q. Not a toxicologist?      14 A. No.      15 Q. Not a biostatistician?      16 A. What?      17 Q. A biostatistician?      18 A. A biostatistician, I do a lot of      19 statistical analysis, but bio, not a      20 biostatistician.      21 Q. Are you an epidemiologist?      22 A. No, I'm not.      23 Q. Are you an expert in biomaterials?      24 MR. JACKSON: Objection, form.</p>
<p style="text-align: right;">Page 19</p> <p>1 Q. You don't consider yourself an FDA expert,      2 do you?      3 MR. JACKSON: Objection, form.      4 A. I mean, I have done a lot of interaction      5 with the FDA when I was at Dow, I did a lot of      6 extraction studies and those kind of things to help      7 fill out paperwork for FDA applications.      8 BY MR. HUTCHINSON:      9 Q. Do you consider yourself a regulatory      10 expert?      11 MR. JACKSON: Objection, form.      12 A. Again, I have done a lot of interaction      13 with government regulatory agencies.      14 BY MR. HUTCHINSON:      15 Q. I understand that, but do you hold      16 yourself out as an expert, sir?      17 MR. JACKSON: Objection to form.      18 A. With regard to FDA?      19 BY MR. HUTCHINSON:      20 Q. Yes.      21 A. I know a lot about it. That's all I can      22 say.      23 Q. I understand, but my question is: Do you      24 consider yourself a regulatory or FDA expert?</p>	<p style="text-align: right;">Page 21</p> <p>1 A. I have done a lot of work with different      2 biomaterials. Again, it's difficult to quantify      3 expert or non-expert, but I have experience working      4 with biomaterials.      5 BY MR. HUTCHINSON:      6 Q. So it is difficult for you to quantify      7 whether or not you are an expert in biomaterials?      8 Did I understand your testimony correctly?      9 MR. JACKSON: Objection, form.      10 A. It's a non-quantifiable question, in my      11 thinking.      12 BY MR. HUTCHINSON:      13 Q. Do you consider yourself an expert, sir,      14 in biomaterials?      15 MR. JACKSON: Objection, asked and      16 answered.      17 A. All I can say is I know a lot about      18 biomaterials.      19 BY MR. HUTCHINSON:      20 Q. Do you consider yourself an expert, is my      21 question?      22 MR. JACKSON: Objection to form.      23 A. I'm an expert in materials.      24 BY MR. HUTCHINSON:</p>

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<p style="text-align: right;">Page 22</p> <p>1 Q. What about biomaterials? 2 A. And biomaterials are included in 3 materials. 4 Q. Are you an expert in biocompatibility? 5 A. Again, I know a lot about 6 biocompatibility. It's just difficult for me to 7 give a yes-no answer to that when I know a lot about 8 it, but, yeah. 9 Q. Doctor, are you an expert in the 10 biological response to foreign bodies? 11 MR. JACKSON: Objection, form. 12 A. Again, I know a lot about it but I'm 13 not a pathologist, so. 14 BY MR. HUTCHINSON: 15 Q. Do you consider yourself an expert in the 16 biological response to foreign bodies? 17 MR. JACKSON: Objection, form. 18 A. I'll just say I know a lot about it. 19 BY MR. HUTCHINSON: 20 Q. You won't answer that question? 21 A. I just did. 22 MR. JACKSON: He just gave the 23 answer. 24 A. It's not a simple yes-no answer.</p>	<p style="text-align: right;">Page 24</p> <p>1 ASTM D3895 and ASTM 1980, correct? 2 MR. JACKSON: Object to the form. 3 A. 1980, no, I did the ASTM D3895. 4 BY MR. HUTCHINSON: 5 Q. Did you follow the protocols from the ASTM 6 1980? 7 A. I would say no. The 1980 is specific to 8 packaging for medical devices, and so I didn't, 9 since this was not packaging for a medical device, I 10 did not follow that. 11 Q. Doctor, your expert report, Page 3, states 12 that you followed the Q10 protocol as described in 13 ASTM F1980, correct? 14 A. Correct. 15 Q. What was the Q10 protocol that you 16 followed? 17 A. That protocol is basically a mathematical 18 protocol where you operate under the assumption, and 19 it is an assumption, that the oxidation rate or 20 reaction rate doubles the kinetics of the oxidation 21 reaction, doubles every 10 degrees Centigrade 22 increase in temperature. So that protocol is used 23 to extrapolate from the elevated temperature to make 24 predictions, and I emphasize the word predictions,</p>
<p style="text-align: right;">Page 23</p> <p>1 BY MR. HUTCHINSON: 2 Q. Do you consider yourself an expert in the 3 design of surgical mesh? 4 MR. JACKSON: Objection, form. 5 A. As far as the design includes materials 6 selection for it, yes. 7 BY MR. HUTCHINSON: 8 Q. Do you consider yourself an expert in 9 female anatomy? 10 A. No. 11 Q. Doctor, let's talk about the testing you 12 did. You did some accelerated aging testing; is 13 that correct? 14 MR. JACKSON: Objection, form. 15 A. The testing I did was called oxidation 16 induction time testing. It is an accelerated test, 17 yes. 18 BY MR. HUTCHINSON: 19 Q. And at what temperature did you do it? 20 A. 200 degrees Centigrade. 21 Q. Why did you choose that number? 22 A. Because it's the recommended temperature 23 in the ASTM D3895 OIT testing standard. 24 Q. And you followed the protocols from the</p>	<p style="text-align: right;">Page 25</p> <p>1 because that's all it is, of what would happen at 2 the lower temperatures. So that's what's referred 3 to by the Q10 protocol. 4 Q. Is the Q10 protocol defined in the ASTM 5 1980 protocol? 6 MR. JACKSON: Objection, form. 7 A. Yes. 8 BY MR. HUTCHINSON: 9 Q. Is that what you followed? 10 MR. JACKSON: Objection, form. 11 A. I followed the Q10 protocol regarding the 12 doubling of reaction rate every 10 degrees. That 13 methodology for calculation is what I followed. 14 BY MR. HUTCHINSON: 15 Q. Did you follow anything else from ASTM 16 1980? 17 MR. JACKSON: Objection, form. 18 A. No. 19 BY MR. HUTCHINSON: 20 Q. Are you giving any life expectancy 21 opinions regarding Prolene? 22 MR. JACKSON: Objection, form. 23 A. No, other than just general, not specific. 24 BY MR. HUTCHINSON:</p>

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<p style="text-align: right;">Page 26</p> <p>1 Q. Are your general life expectancy opinions 2 regarding Prolene included in your expert report? 3 A. My expert opinion is that its life 4 expectancy is not indefinite, that it degrades so 5 it's not going to last forever. 6 Q. But you are not giving any specific life 7 expectancy opinions, are you, sir? 8 MR. JACKSON: Objection, form. 9 A. No. 10 (Priddy Deposition Exhibit 4 was 11 marked for identification.) 12 BY MR. HUTCHINSON: 13 Q. I hand you what we'll mark as Exhibit 4 to 14 your deposition. 15 (Witness reviewing document.) 16 Q. This is the ASTM that you followed, 17 correct? 18 A. Yes. 19 Q. Is this the version that you followed? 20 A. I'm not sure if it's the dash 14 version 21 or not. I would think it probably is not the dash 22 14 version. It's probably an earlier version, 23 because I have been doing OIT for many years, much 24 earlier than 2014.</p>	<p style="text-align: right;">Page 28</p> <p>1 Q. Doctor, on Page 2 of your expert report, 2 you did what is called oxidative induction time 3 testing; is that correct? 4 A. Correct. 5 Q. You generated some -- I'm going to call 6 that, by the way, OIT for short. Are you and I on 7 the same page? 8 A. Absolutely. 9 Q. You generated some OIT values contained in 10 your report; is that right? 11 A. That is correct. 12 Q. And you used OIT to compare the oxidative 13 stability of 10 different Ethicon mesh samples? 14 A. That's correct. 15 Q. Who conducted the tests? 16 A. A technician at Materials Engineering, 17 Inc. located in Virgil, Illinois. They are an A2LA 18 certified laboratory. 19 Q. How far away is that from your office? 20 A. About 180 miles probably. 21 Q. Do you know the names of the person who 22 did the testing? 23 A. Yes. 24 Q. What were their names?</p>
<p style="text-align: right;">Page 27</p> <p>1 Q. But 2014 -- or 14, rather, stands for 2 the year, correct? 3 A. Correct. 4 Q. You used an older version of the ASTM 5 3895? 6 MR. JACKSON: Objection, form. 7 A. Yes. 8 BY MR. HUTCHINSON: 9 Q. Why? 10 A. Because I have been doing it for many 11 years preceding '14, and once I get the lab set up 12 doing a specific test, following a specific standard 13 in a specific way, I just don't deviate it. 14 Q. Sir, did you ever compare the version, the 15 older version that you used of 3895 to the most 16 recent ASTM 3895 2014? 17 A. No. 18 Q. Are you aware of any changes between those 19 two ASTM protocols? 20 A. I would have to study it in depth to look 21 for those differences. 22 Q. But you can't tell us those differences 23 now? 24 A. No.</p>	<p style="text-align: right;">Page 29</p> <p>1 A. Steve Johnson is the technician that runs 2 that test. 3 Q. Were you present when Steve Johnson did 4 any of the tests? 5 A. No. 6 Q. Did you direct the work of Steve Johnson 7 in any way? 8 MR. JACKSON: Objection, form. 9 A. To the extent of how I wanted the mesh 10 samples analyzed, yes. 11 BY MR. HUTCHINSON: 12 Q. Did you provide any written correspondence 13 to Steve Johnson on how to do the tests? 14 A. No. 15 Q. Do you know how long Steve Johnson took to 16 do the tests? 17 MR. JACKSON: Objection, form. 18 A. About a week. 19 BY MR. HUTCHINSON: 20 Q. Eight hours a day? 21 A. I wasn't there to watch him. I don't 22 know. 23 Q. Do you know how much specific time Steve 24 Johnson did in doing the tests?</p>

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<p style="text-align: right;">Page 30</p> <p>1 A. No.      2 Q. Has Steve Johnson sent you a bill for      3 doing those tests?      4 A. I have a credit card on file with him and      5 when he's done, he just charges my card.      6 Q. Has he charged your card yet?      7 A. I have to check. I don't recall offhand.      8 Q. Do you have any idea how much money Steve      9 Johnson is going to charge you to do the tests that      10 are outlined in your expert report?      11 A. Well, I know that he charges me about \$200      12 to run an OIT test and since he ran these ten tests,      13 I can do the math.      14 Q. Doctor, do you know if Steve Johnson had      15 any help doing the tests?      16 A. He has another technician that works with      17 him.      18 Q. What's that technician's name?      19 A. It was a new hire. I don't even recall,      20 Mark somebody.      21 Q. Do you know how this new hire has been      22 trained?      23 A. I don't.      24 Q. Have you ever met this new hire?</p>	<p style="text-align: right;">Page 32</p> <p>1 handled the mesh, correct?      2 A. That is correct.      3 Q. Have you ever asked for any chain of      4 custody documents from Steve Johnson?      5 A. I just talked to him to make sure that he      6 received them. He said yes, I have. But I confirmed      7 his receipt of the meshes that I sent to him.      8 Q. But you have no chain of custody documents      9 showing what Steve Johnson did with the mesh,      10 correct?      11 MR. JACKSON: Objection, form.      12 A. I know he received them and analyzed them      13 and he still has them.      14 BY MR. HUTCHINSON:      15 Q. How did you ship the samples to Steve      16 Johnson?      17 A. UPS.      18 Q. Where did you get the samples to ship to      19 Steve Johnson?      20 A. From Fidelma, an attorney.      21 Q. When did you receive them?      22 A. I'd have to look at the chain of custody      23 documents. I believe it was mid-December.      24 Q. What products did you receive?</p>
<p style="text-align: right;">Page 31</p> <p>1 A. No.      2 Q. Do you know how much time this new hire      3 named Mark spent on this test?      4 MR. JACKSON: Objection, form.      5 A. I don't think he has done anything on the      6 test. I think Steve Johnson did it all.      7 BY MR. HUTCHINSON:      8 Q. And Steve Johnson did this DSC test,      9 correct?      10 A. That's correct.      11 Q. Differential scanning calorimetry?      12 A. That's correct.      13 Q. He used some samples of Ethicon's mesh,      14 right?      15 A. That's correct.      16 Q. Did you give the samples to Steve Johnson?      17 A. I sent them to him.      18 Q. Is that reflected in the chain of custody      19 documents?      20 A. It is.      21 Q. Have you ever received any chain of      22 custody documents from Steve Johnson?      23 A. No.      24 Q. Steve Johnson was the one who actually</p>	<p style="text-align: right;">Page 33</p> <p>1 A. I received six different TVTs and four      2 different Gynemeshes.      3 Q. Would you describe the Gynemeshes that you      4 received?      5 A. Describe them?      6 Q. Yes, sir.      7 MR. JACKSON: Objection, form.      8 BY MR. HUTCHINSON:      9 Q. Describe them for the jury. What did they      10 look like?      11 A. It's just a strip of polypropylene mesh      12 between, I assume, some stainless steel rods.      13 Q. How else would you describe the Gynemesh      14 that you received?      15 MR. JACKSON: Objection, form.      16 A. That's about all I can say about it.      17 BY MR. HUTCHINSON:      18 Q. How was the Gynemesh that you received      19 with the two stainless rods different from the six      20 TVTs that you received?      21 MR. JACKSON: Objection, form.      22 A. They both had mesh between metal rods and      23 I didn't specifically study exactly how they were      24 different so I can't answer that question.</p>

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<p style="text-align: right;">Page 34</p> <p>1 BY MR. HUTCHINSON:</p> <p>2 Q. So all products that you received had mesh 3 between two stainless steel rods; is that correct?</p> <p>4 A. That's my recollection, yes.</p> <p>5 Q. Doctor, let's talk about the sampling that 6 was used for the DSC. DSC is a test, by the way, 7 right?</p> <p>8 A. Yes.</p> <p>9 Q. That's an analytical test?</p> <p>10 A. It's a piece of equipment.</p> <p>11 Q. And the purpose of the equipment is in 12 essence to melt the product inside, fair enough?</p> <p>13 MR. JACKSON: Objection, form.</p> <p>14 A. No.</p> <p>15 BY MR. HUTCHINSON:</p> <p>16 Q. What's the purpose of the equipment?</p> <p>17 A. It's to detect thermal heat flow, whether 18 it be cooling or heating with plastic materials.</p> <p>19 Q. But you do that by melting the plastic 20 material, correct?</p> <p>21 MR. JACKSON: Objection, form.</p> <p>22 A. Not necessarily.</p> <p>23 BY MR. HUTCHINSON:</p> <p>24 Q. Did you melt the samples that you received</p>	<p style="text-align: right;">Page 36</p> <p>1 A. Because it wasn't relevant to my opinion.</p> <p>2 Q. Doctor, was this test sample compressed or 3 molded into a sheet format?</p> <p>4 A. No.</p> <p>5 Q. Why not?</p> <p>6 A. Because that would have given the sample 7 another heat history, and I wanted to have the 8 samples tested in their original use shape as 9 monofilaments.</p> <p>10 Q. How many times was the DSC test run?</p> <p>11 MR. JACKSON: Objection, form.</p> <p>12 A. It's run once, and I had him run it in 13 pure oxygen, switching from nitrogen to oxygen, and 14 I also asked him to run it switching from nitrogen 15 to air, so he ran it twice for each sample.</p> <p>16 BY MR. HUTCHINSON:</p> <p>17 Q. Do you know how long he ran it in pure 18 nitrogen?</p> <p>19 A. You run it for so many minutes until the 20 equipment is stable, get a smooth baseline. That's 21 generally five minutes or so at 200.</p> <p>22 Q. But my question is, do you know how long 23 Steve Johnson ran it in pure nitrogen?</p> <p>24 A. Whatever the standard dictates, and I</p>
<p style="text-align: right;">Page 35</p> <p>1 in this case?</p> <p>2 A. At 200 degrees, that's above the melting 3 point so they would be melted, yes.</p> <p>4 Q. How did you make the specimen sample?</p> <p>5 A. It was cut with scissors.</p> <p>6 Q. In your lab or in Steve Johnson's lab?</p> <p>7 A. Steve Johnson did the cutting.</p> <p>8 Q. Were you supervising the cutting of the 9 samples with Steve Johnson?</p> <p>10 A. I was not present, but we discussed the 11 protocol of how to collect the samples.</p> <p>12 Q. What was the average sheet thickness of 13 the sample?</p> <p>14 MR. JACKSON: Objection, form.</p> <p>15 A. I don't recall.</p> <p>16 BY MR. HUTCHINSON:</p> <p>17 Q. Did you ever ask Steve Johnson about what 18 the average sheet thickness was of the sample?</p> <p>19 A. I asked him what the thickness was.</p> <p>20 Q. What did he tell you?</p> <p>21 A. I don't recall. It was less than -- I 22 don't recall.</p> <p>23 Q. Why is that not included in your expert 24 report?</p>	<p style="text-align: right;">Page 37</p> <p>1 believe it's five minutes.</p> <p>2 Q. Do you know how long Steve Johnson ran the 3 sample or ran the test, rather, in pure oxygen?</p> <p>4 MR. JACKSON: Objection, asked and 5 answered.</p> <p>6 A. It's in the data. Once you switch from 7 nitrogen to oxygen, that's time 0, and then you run 8 it in pure oxygen until the exotherm is over and 9 that gives you your OIT data.</p> <p>10 BY MR. HUTCHINSON:</p> <p>11 Q. Let's look at Exhibit 4 and turn with me 12 to Page 2.</p> <p>13 A. Okay.</p> <p>14 Q. Under "9. sampling." Do you see that?</p> <p>15 A. Yes.</p> <p>16 Q. 9.1 says, "The following sample 17 preparation procedures are recommended: the test 18 sample is compression molded into sheet format." 19 Did I read that correctly?</p> <p>20 A. Absolutely.</p> <p>21 Q. Why did you not follow that protocol?</p> <p>22 MR. JACKSON: Objection, form.</p> <p>23 A. Because it's recommended and, as I said 24 previously, that would require another heat history</p>

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<p style="text-align: right;">Page 38</p> <p>1 on the sample, and I wanted to look at pristine mesh 2 samples in their use state. And I didn't want to 3 alter that. 4 So that would have affected the results to 5 have done it that way. And I emphasize the word 6 "recommended," because you don't have to do it that 7 way, it's just the recommended. 8 Q. I understand, but fair to say that you 9 didn't follow the recommended sampling procedure in 10 ASTM 3895, correct? 11 MR. JACKSON: Objection, form. 12 A. Absolutely for good reason, it would have 13 affected the results negatively. 14 BY MR. HUTCHINSON: 15 Q. Doctor, there is nothing in your expert 16 report about how the samples were prepared, is 17 there? 18 A. Not in the report directly, no. 19 Q. Why did you not include that in your 20 expert report? 21 A. Because it has no bearing on my opinions. 22 Q. Doctor, did you do any type of statistical 23 calculations to confirm that the results you got 24 from this test that Steve Johnson did were</p>	<p style="text-align: right;">Page 40</p> <p>1 numbers data gave a correlation with the level of 2 antioxidant in the mesh samples. And the reason I 3 did that is just to confirm that there's a 4 statistical correlation between the level of 5 antioxidant and the OIT values because if there 6 hadn't have been, then I would have been concerned 7 about the validity of the results. 8 Q. Doctor, let's look at Exhibit 4 for a 9 minute. This is that ASTM 3895. 10 A. Yes. 11 Q. Bottom of Page 1, 4.3 states, "Unless 12 otherwise specified, the analysis temperature used 13 in this test has been arbitrarily set at 200 degrees 14 C." 15 Do you see that? 16 A. Yes. 17 Q. That's the temperature you used? 18 A. Correct. 19 Q. You used an arbitrary number? 20 MR. JACKSON: Objection, form. 21 A. I used the number specified in the 22 standard, yes. 23 BY MR. HUTCHINSON: 24 Q. And the number specified in the standard</p>
<p style="text-align: right;">Page 39</p> <p>1 statistically significant? 2 MR. JACKSON: Objection, form. 3 A. What I did do -- 4 BY MR. HUTCHINSON: 5 Q. We are going to get to what you did do in 6 a minute. I want to know the answer to my question 7 first and then we'll get there. 8 MR. JACKSON: Counsel, you have to 9 let him answer the question. 10 BY MR. HUTCHINSON: 11 Q. Did you do any type of statistical 12 calculations to -- 13 A. Yes. 14 Q. Are those statistical calculations 15 included in your expert report? 16 A. No. 17 Q. Why not? 18 A. Just didn't include it. 19 Q. Any reason? 20 A. No. 21 Q. What type of statistical calculations did 22 you do? 23 A. I had Steve Johnson extract the additives 24 from the mesh samples and to determine if the OIT</p>	<p style="text-align: right;">Page 41</p> <p>1 is an arbitrary number, correct? 2 MR. JACKSON: Objection, form. 3 A. It is the number that I run. Every time I 4 do an OIT test I do it at 200 degrees. That's just 5 always the way I run it. 6 BY MR. HUTCHINSON: 7 Q. I understand that, but the number that you 8 used is an arbitrary number according to the ASTM 9 standard, correct? 10 MR. JACKSON: Objection, form. 11 A. If they -- they define it as an arbitrary 12 number, so. 13 BY MR. HUTCHINSON: 14 Q. Doctor, would you ever attempt to publish 15 a paper in a peer-reviewed journal using arbitrary 16 data? 17 MR. JACKSON: Objection, form. 18 A. I certainly would attempt to publish an 19 article in a paper based upon following an ASTM 20 standard. 21 BY MR. HUTCHINSON: 22 Q. Would you ever attempt to publish anything 23 in a peer-reviewed journal with an arbitrary number? 24 MR. JACKSON: Objection, form.</p>

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<p style="text-align: right;">Page 42</p> <p>1 A. If it is specified in the standard, yes.      2 BY MR. HUTCHINSON:      3 Q. Doctor, your report states that the mesh      4 sample was heated to 200 degrees under pure      5 nitrogen; is that right?      6 A. Yes.      7 Q. That's the temperature at which you      8 conducted this aging study?      9 MR. JACKSON: Objection, form.      10 A. Correct.      11 BY MR. HUTCHINSON:      12 Q. That's also known as the accelerated aging      13 temperature, correct?      14 A. Yes.      15 Q. That equates to roughly 392 degrees      16 Fahrenheit?      17 A. Correct.      18 Q. That's about 300 degrees Fahrenheit above      19 the normal temperature of a human being; is that      20 correct?      21 A. Correct.      22 Q. And it is well above the melting point of      23 Prolene, isn't it?      24 MR. JACKSON: Objection, form.</p>	<p style="text-align: right;">Page 44</p> <p>1 testing. If there's a red flag there, it will just      2 give you a red flag. And so with that      3 understanding, as I say, I routinely use this test      4 for doing lifetime predictions.      5 Q. I understand, but with that understanding,      6 a qualitative test does not give you lifetime      7 predictions, does it?      8 MR. JACKSON: Objection, form.      9 A. Yeah, It gives you predictions, certainly.      10 BY MR. HUTCHINSON:      11 Q. It doesn't give you lifetime facts or      12 lifetime specifics, does it?      13 MR. JACKSON: Objection, form.      14 A. Every time you use an accelerated test      15 protocol to get a prediction, it's only a prediction      16 and you have to follow it up with real life, live      17 tests to validate.      18 BY MR. HUTCHINSON:      19 Q. And you have to follow it up with real      20 time aging tests, correct?      21 MR. JACKSON: Objection, form.      22 A. That is correct.      23 BY MR. HUTCHINSON:      24 Q. Doctor, you wouldn't rely on a qualitative</p>
<p style="text-align: right;">Page 43</p> <p>1 A. Yes, it is.      2 BY MR. HUTCHINSON:      3 Q. What is the melting point of Prolene?      4 A. 165 degrees Centigrade approximately.      5 Q. Doctor, moving to Page 2, at the top under      6 Significance and Use, are you there with me?      7 A. Yes.      8 Q. It says, "The OIT is a qualitative      9 assessment of the level (or degree) of stabilization      10 of the material tested."      11 Do you see that?      12 A. Yes.      13 Q. And a qualitative test is different from a      14 quantitative test, isn't it, sir?      15 A. That's correct.      16 Q. A qualitative test doesn't give you a      17 lifetime prediction, does it?      18 MR. JACKSON: Objection, form.      19 BY MR. HUTCHINSON:      20 Q. Doctor?      21 A. It's standard practice to use data from      22 these kind of tests to do lifetime predictions,      23 realizing it's only a prediction. With that      24 understanding that it has to be validated by actual</p>	<p style="text-align: right;">Page 45</p> <p>1 test to determine how long a polymer would retain      2 its physical properties, would you?      3 MR. JACKSON: Objection, form.      4 A. I would use it for predictive purposes,      5 yes.      6 BY MR. HUTCHINSON:      7 Q. Doctor, let's move on to the top of Page      8 2. Under Note 2 it states, "The OIT measurement is      9 an accelerated thermal-aging test and as such can be      10 misleading."      11 Did I read that correctly?      12 A. Yes.      13 Q. What does misleading mean?      14 MR. JACKSON: Objection, form.      15 A. What they are trying to say there is, if I      16 have different materials, say two different      17 polypropylenes with two different stabilizer      18 packages, one polypropylene has additive stabilizer      19 antioxidant A in it and another one has antioxidant      20 stabilizer package B in it and I run an OIT and I      21 get different values, that it would be misleading      22 for me to say that one is better than the other.      23 BY MR. HUTCHINSON:      24 Q. Did you consider this statement before</p>

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<p style="text-align: right;">Page 46</p> <p>1 doing your testing?</p> <p>2 MR. JACKSON: Objection, form.</p> <p>3 A. Yes.</p> <p>4 BY MR. HUTCHINSON:</p> <p>5 Q. Doctor, one would never expect to use 6 Prolene in the body at 200 degrees C, would they?</p> <p>7 A. That's correct.</p> <p>8 Q. In fact, you would never expect Prolene to 9 be exposed to a hundred percent nitrogen in vivo, 10 would you?</p> <p>11 A. No.</p> <p>12 Q. You'd never expect Prolene to be exposed 13 to a hundred percent oxygen in vivo, would you?</p> <p>14 MR. JACKSON: Objection, form.</p> <p>15 A. Not pure oxygen. I certainly would expect 16 it to be exposed to oxidizing species, but not a 17 hundred percent pure oxygen, no.</p> <p>18 BY MR. HUTCHINSON:</p> <p>19 Q. Moving on down on Note 2, last sentence it 20 says, "Volatile antioxidants may generate poor OIT 21 results even though they may perform adequately at 22 the intended use temperature of the finished 23 product."</p> <p>24 Did I read that correctly?</p>	<p style="text-align: right;">Page 48</p> <p>1 level of volatility.</p> <p>2 If it comes through in less than 10 3 minutes, it is volatile. If it takes 20 minutes to 4 come off the GC column, you know that at 5 200 degrees, it is not volatile. And I did the same 6 thing for Santonox R.</p> <p>7 Q. Doctor, did you account for the volatility 8 of any other additives contained in Prolene?</p> <p>9 A. No, I was focused on the antioxidant 10 species.</p> <p>11 Q. Did you focus any on Procol LA-10?</p> <p>12 A. No.</p> <p>13 Q. Did you ever focus on calcium stearate?</p> <p>14 A. No. Those are lubricants, not 15 antioxidants.</p> <p>16 Q. Doctor, the intended use temperature of 17 the finished product, what is the intended use 18 temperature of the finished product?</p> <p>19 MR. JACKSON: Objection, form.</p> <p>20 A. 37 degrees C or 98.6 Fahrenheit.</p> <p>21 BY MR. HUTCHINSON:</p> <p>22 Q. It is not 200 degrees C, is it?</p> <p>23 A. No.</p> <p>24 Q. Doctor, moving on down to Note 3, "There</p>
<p style="text-align: right;">Page 47</p> <p>1 A. Yes.</p> <p>2 Q. Did you consider that before you did your 3 testing, Doctor?</p> <p>4 A. Yes.</p> <p>5 Q. Do you know whether there is a volatile 6 antioxidant in Prolene?</p> <p>7 A. The Santonox R and the dilauryl 8 thiodipropionate, both of those additives are not 9 volatile. At 200 degrees they would not vaporize 10 from the Prolene.</p> <p>11 Q. What do you base that on, Doctor?</p> <p>12 A. Just my polymer chemistry and experience 13 working with these types of antioxidants.</p> <p>14 Q. Did you account for the volatility of 15 DLTPD before you did your testing?</p> <p>16 A. Yes.</p> <p>17 Q. How?</p> <p>18 A. I actually asked the technician to inject 19 a sample of pure dilauryl thiodipropionate -- this 20 is Steve Johnson -- into the gas chromatograph to 21 determine its relative volatility. In other words, 22 you do that by retention time, how long does it take 23 this chemical to -- before it makes its way through 24 the gas chromatograph, and you get a feel for its</p>	<p style="text-align: right;">Page 49</p> <p>1 is no accepted sampling procedure, nor have any 2 definitive relationships been established for 3 comparing OIT values on field samples to those on 4 unused products. Hence, the use of such values for 5 determining life expectancy is uncertain and 6 subjective."</p> <p>7 Did I read that correctly?</p> <p>8 A. Absolutely, yes.</p> <p>9 Q. Doctor, what would the field sample be in 10 this particular case?</p> <p>11 A. The Prolene mesh.</p> <p>12 Q. It would be an explant, correct?</p> <p>13 MR. JACKSON: Objection, form.</p> <p>14 A. No, it's a virgin, unused implant.</p> <p>15 BY MR. HUTCHINSON:</p> <p>16 Q. That's what you consider to be a field 17 sample?</p> <p>18 A. Yes.</p> <p>19 Q. What's the difference between a virgin, 20 unused piece of Prolene and an unused product?</p> <p>21 MR. JACKSON: Objection, form.</p> <p>22 A. There is no difference.</p> <p>23 BY MR. HUTCHINSON:</p> <p>24 Q. Doctor, the ASTM that you quote says</p>

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<p>1 there have been no definitive relationships      2 established for comparing values on field samples to      3 those for unused products.</p> <p>4 MR. JACKSON: Objection, misstates      5 witness testimony.</p> <p>6 BY MR. HUTCHINSON:</p> <p>7 Q. That's what the ASTM says, correct?</p> <p>8 A. Okay.</p> <p>9 Q. And in fact, Doctor, there's been no      10 definitive relationships established for comparing      11 the OIT values of explant to mesh that's never been      12 used in surgery; is that fair?</p> <p>13 A. That is fair, yes.</p> <p>14 Q. In fact, Doctor, can you stand by your      15 opinions to a reasonable degree of scientific      16 certainty, given that the ASTM that you used says      17 "determining life expectancy is uncertain and      18 subjective"?</p> <p>19 MR. JACKSON: Objection, form.</p> <p>20 A. I'm sorry, I don't understand that      21 question. Would you repeat it, please?</p> <p>22 BY MR. HUTCHINSON:</p> <p>23 Q. Can you stand by your opinions, given that      24 the ASTM that you used says "determining life</p>	<p>1 Q. Doctor, would you ever publish anything in      2 the "American Chemical Society" journal that was      3 uncertain and subjective?</p> <p>4 MR. JACKSON: Objection, form.</p> <p>5 A. Yes, I would.</p> <p>6 BY MR. HUTCHINSON:</p> <p>7 Q. Doctor, moving on down to Note 7, it      8 states, "The material composition of the specimen      9 holder can influence the OIT test result      10 significantly."</p> <p>11 Do you see that?</p> <p>12 A. I'm sorry, where are you at?</p> <p>13 Q. At the bottom of Page 2, note 7.</p> <p>14 A. Reagents and Materials?</p> <p>15 Q. No, bottom of Page 2. It says, "The      16 material composition of the specimen holder."</p> <p>17 Do you see that?</p> <p>18 A. I'm sorry, I'm still not with you.</p> <p>19 Could you point to where you?</p> <p>20 Q. I'll be happy to.</p> <p>21 A. Okay, thank you. Okay.</p> <p>22 Q. Do you see that, Doctor?</p> <p>23 A. Yes.</p> <p>24 Q. What type of specimen holder was used by</p>
Page 51	Page 53
<p>1 expectancy is uncertain and subjective"?</p> <p>2 MR. JACKSON: Objection, form.</p> <p>3 A. What I can say is this, the life      4 expectancy is uncertain, that's correct.</p> <p>5 BY MR. HUTCHINSON:</p> <p>6 Q. And the life expectancy is also      7 subjective, isn't it, sir?</p> <p>8 MR. JACKSON: Objection, form.</p> <p>9 A. All I can say is in a nutshell, this data      10 shows that the Prolene material will not last      11 indefinitely in the body. It is susceptible to      12 oxidative degradation over time.</p> <p>13 BY MR. HUTCHINSON:</p> <p>14 Q. But the life expectancy is subjective,      15 isn't it, sir?</p> <p>16 MR. JACKSON: Objection, form.</p> <p>17 A. It is subject to the conditions in the      18 body, yes, certainly.</p> <p>19 BY MR. HUTCHINSON:</p> <p>20 Q. It is also subjective according to the      21 ASTM protocol, correct?</p> <p>22 A. It's always subjective, lifetime of any      23 article is subject to the conditions that the part      24 is under, exposed to.</p>	<p>1 Steve Johnson?</p> <p>2 A. It's called a DSC pan.</p> <p>3 Q. What is the DSC pan that Steve Johnson      4 used made out of?</p> <p>5 A. He told me. It's in the report and I      6 don't recall offhand.</p> <p>7 Q. It is in your expert report?</p> <p>8 A. No, it's in his report to me.</p> <p>9 Q. Steve Johnson prepared a report and gave      10 it to you?</p> <p>11 MR. JACKSON: Objection, form.</p> <p>12 A. It's data. He gives me the data with a      13 little note and it tells what the pan is, but I      14 don't recall offhand what the pan is.</p> <p>15 BY MR. HUTCHINSON:</p> <p>16 Q. Where is the data that Steve Johnson gave      17 you?</p> <p>18 A. It would be on my computer.</p> <p>19 Q. It is not included on this flash drive, is      20 it, sir?</p> <p>21 A. It probably is.</p> <p>22 Q. Can you testify under oath that this data      23 that Steve Johnson gave you is contained on this      24 flash drive?</p>

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<p style="text-align: right;">Page 54</p> <p>1        MR. JACKSON: Objection, form.      2        A. Not without checking to confirm for sure.      3 I believe I put it on there.      4 BY MR. HUTCHINSON:      5        Q. Doctor, sitting here today, can you tell      6 us the type of specimen holder that Steve Johnson      7 used?      8        A. A DSC pan, and I don't recall what the      9 metal was.      10      Q. Do you know if Steve Johnson used more      11 than one specimen holder?      12      A. The little DSC pans are disposable. In      13 other words, for the OIT test, he uses a specific      14 type of pan that he knows to be, not influence the      15 data and that's the type of pan he uses. I just      16 don't recall offhand what the metal is.      17      Q. Doctor, have you done anything to      18 determine if the specimen holder that Steve Johnson      19 used affected the results?      20      MR. JACKSON: Objection, form.      21      A. As I say, he in the past has run tests,      22 since he runs the OIT for me all the time, to      23 confirm the OIT test as he runs it is unaffected by      24 the pan that he uses. It's just I don't recall what</p>	<p style="text-align: right;">Page 56</p> <p>1 processes checked by auditors.      2        And so the DSC pan is always the same.      3 It's been confirmed by him not to affect the      4 results. That's the pan he used. I just can't      5 recall what the metal is offhand.      6        Q. That's right. But my question to you is:      7 Have you personally -- I'm not talking about Steve      8 Johnson, I'm talking about you personally -- have      9 you personally done anything to determine if the      10 specimen holder affected the results?      11      MR. JACKSON: Objection, asked and      12 answered.      13      A. Other than how I have just answered it,      14 no.      15 BY MR. HUTCHINSON:      16      Q. Doctor, can you use your DSC data to make      17 lifetime calculations when one is in pure oxygen and      18 the other is implanted in vivo?      19      MR. JACKSON: Objection, form.      20      A. I wasn't trying to do that. That wasn't      21 the purpose. My purpose for running the test was to      22 look at variability of ten different mesh samples.      23 That was my intent. And so I was looking to see if,      24 when these different samples with the same</p>
<p style="text-align: right;">Page 55</p> <p>1 metal it is.      2 BY MR. HUTCHINSON:      3        Q. I understand that, Doctor, but I'm asking      4 you, have you done anything personally to determine      5 if the specimen holder that Steve Johnson used      6 affected the test results?      7        A. I don't run DSC, so technicians do that.      8        Q. Have you done anything, sir, personally to      9 determine if the specimen holder affected the      10 results?      11      MR. JACKSON: Objection, asked and      12 answered.      13      A. As I say, it was done in the past, on past      14 projects.      15 BY MR. HUTCHINSON:      16      Q. I am talking about this project, sir.      17 Have you personally done anything to determine if      18 the specimen holder affected the results, yes or no?      19      MR. JACKSON: Objection, asked and      20 answered.      21      A. In the sense that I made sure that he is      22 using his standard pan under the standard operating      23 procedures for the laboratory as an A2LA certified      24 laboratory. They are annually audited, all their</p>	<p style="text-align: right;">Page 57</p> <p>1 antioxidant formulations in them, when they are      2 suddenly exposed to oxygen, do they have the same      3 OIT value or is it extremely variable. And I saw up      4 to 150 percent variability from the low to the high      5 end.      6        The key message is that these implants      7 have variability in their oxidation resistance.      8 They aren't all the same. That's it. That's the      9 only message that I was trying to figure out there.      10      (Priddy Deposition Exhibit 5 was      11 marked for identification.)      12 BY MR. HUTCHINSON:      13      Q. Doctor, handing you what we'll mark as      14 Exhibit 5 to your deposition. This is the ASTM      15 that you quoted in your expert report, correct?      16      MR. JACKSON: Objection, form.      17      A. Yes.      18 BY MR. HUTCHINSON:      19      Q. I believe it is your testimony, you didn't      20 follow this ASTM 1980 protocol; is that right?      21      A. The only portion that I followed is this      22 Q10 estimate for trying to get a feel for predicting      23 lifetimes.      24      Q. Why didn't you follow anything else?</p>

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1           MR. JACKSON: Objection, form. 2       A. Because it's not a -- it has to do with 3     sterile medical device packages, not what's inside. 4     So it's really not a standard that's directly 5     applicable to this situation. 6    BY MR. HUTCHINSON: 7       Q. Doctor, fair to say you never did any 8     real-time aging studies to confirm the accelerated 9     aging study results that you generated, correct? 10      A. That is correct. 11      Q. All of the studies that you did are 12     contained in your expert report; is that correct? 13      MR. JACKSON: Objection, form. 14      A. I mean, I mentioned a few minutes ago, I 15     ran the OIT test under pure oxygen and then 16     switching from nitrogen to air, and I believe that's 17     the only deviation that was done that wasn't 18     included in the report. 19    BY MR. HUTCHINSON: 20      Q. Doctor, turn with me to Page 2. 21      A. Of? 22      Q. Of Exhibit 5 which is ASTM 1980. 23      A. Yes. 24      Q. There on Page 2, note 6.4, this is a	1           MR. JACKSON: Objection, form. 2       A. No, it's just a normal, understood 3     scientific principle that reaction rates 4     approximately double every 10 degrees. 5       Q. Is that based on any scientific literature 6     that you can tell me sitting here today? 7       A. I could, if I was pressed to do so, I 8     could come up with textbook references, organic 9     chemistry 101, polymer chemistry 101 where they 10    teach this doubling of a reaction rate every 11    10-degree principle. As I say, it's crude and it's 12    just for ballpark, is there a flag, kind of 13    calculations. 14      Q. But it is your testimony, if I understand 15     it, under oath that ASTM 1980 does not apply to the 16     testing you did, correct? 17      MR. JACKSON: Objection, form. 18      A. Yes, because it's for packaging. The only 19     reason I reference it is because of that Q10 20     doubling of reaction rate principle. 21      MR. JACKSON: Chad, we have been 22     going just about an hour. Are we at a 23     good time for a break? 24      MR. HUTCHINSON: One more thing and
Page 59	Page 61
1     protocol that you followed in determining the Q10 2     level, correct? 3       MR. JACKSON: Objection, form. 4       A. Q10. 5    BY MR. HUTCHINSON: 6       Q. Am I correct? 7       A. Not really, because they talk about three 8     temperatures here and I only ran one temperature, 9     200. 10      Q. Doctor, did you follow any type of 11     protocol in your Q10 calculations for determining 12     the temperature that you used? 13      MR. JACKSON: Objection, form. 14      A. The temperature that I used? 15    BY MR. HUTCHINSON: 16      Q. Strike that. What did you use Q10 for? 17      A. The only portion of this that I used was 18     just what I described earlier, the doubling, 19     approximately doubling of reaction rate every 20     10 degrees. That's the only -- I just referenced 21     this to support that concept for doing that crude 22     calculation. That's all. 23      Q. Doctor, the double reaction rate for every 24     10 degrees, is that based on any ASTM standard?	1     we'll take a quick break, okay? 2       (Priddy Deposition Exhibit 6 was 3     marked for identification.) 4    BY MR. HUTCHINSON: 5       Q. Doctor, handing you what we'll mark as 6     Exhibit 6 to your deposition. This is the 7     de la Rie article that you quoted in your expert 8     report; is that correct? 9       (Witness reviewing document.) 10      A. Yes. 11      Q. Did you read this before you quoted it in 12     your expert report? 13      A. Yes. 14      Q. Turn to Page 17 with me, please. 15      A. Okay. 16      Q. At the bottom of the column on the left, 17     the paragraph starting out with "Materials," are 18     you there with me? 19      A. Yes. 20      Q. It states, "Materials which are not 21     exposed to light" -- and by the way, mesh when 22     planted in vivo is not exposed to light, is it? 23      MR. JACKSON: Objection, form. 24      A. No. Not while it is in vivo, it is not.

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<p style="text-align: right;">Page 62</p> <p>1 BY MR. HUTCHINSON:</p> <p>2 Q. "Materials which are not exposed to light 3 during their normal life could be tested in heat 4 aging experiments."</p> <p>5 In fact, that's what you did, correct, a 6 heat aging experiment, correct, on mesh?</p> <p>7 MR. JACKSON: Objection, form.</p> <p>8 A. Yes, I did.</p> <p>9 BY MR. HUTCHINSON:</p> <p>10 Q. It goes on to say, "But if temperatures 11 are used which are considerably higher than the ones 12 the material is exposed to under normal 13 circumstances, the danger exists of introducing new 14 degradation reactions."</p> <p>15 Did I read that correct?</p> <p>16 A. Yes, you did.</p> <p>17 Q. Doctor, did you consider that before you 18 did your accelerated aging tests?</p> <p>19 A. Yes.</p> <p>20 Q. Did you know what de la Rie said about 21 using higher temperatures?</p> <p>22 A. Yes.</p> <p>23 Q. How did you account for that?</p> <p>24 A. By stating that it is only a rough</p>	<p style="text-align: right;">Page 64</p> <p>1 time is 10:08 a.m.</p> <p>2 BY MR. HUTCHINSON:</p> <p>3 Q. Doctor, we are back on the record. Have 4 you understood all my questions so far?</p> <p>5 A. Yes.</p> <p>6 Q. Is there anything about the testimony 7 that you have given that you would like to change?</p> <p>8 MR. JACKSON: Objection, form.</p> <p>9 A. Not at this point.</p> <p>10 BY MR. HUTCHINSON:</p> <p>11 Q. Turn with me to Exhibit 2. That's your 12 expert report.</p> <p>13 A. Okay, got it.</p> <p>14 Q. On Page 3 you state you are a plastics 15 consultant for medical supply companies?</p> <p>16 A. Yes.</p> <p>17 Q. What type of products?</p> <p>18 A. Oh, boy.</p> <p>19 Q. Let me ask you this: Any products 20 regarding polypropylene?</p> <p>21 A. I mean, I have done materials selection 22 work for Baxalta.</p> <p>23 Q. Let's focus on polypropylene.</p> <p>24 A. I considered polypropylene as I was</p>
<p style="text-align: right;">Page 63</p> <p>1 approximation and has to be validated with actual 2 real-time studies because of this possibility.</p> <p>3 Q. Doctor, did you do any type of calculation 4 regarding the Arrhenius rate reaction for 5 polypropylene?</p> <p>6 MR. JACKSON: Objection, form.</p> <p>7 A. That has been done in the literature 8 before.</p> <p>9 BY MR. HUTCHINSON:</p> <p>10 Q. I am asking you: Did you do any 11 calculation for the Arrhenius rate reaction for 12 polypropylene?</p> <p>13 MR. JACKSON: Objection, form.</p> <p>14 A. Not on my data, no, I couldn't, because I 15 only ran at one temperature. I did not run at 16 three temperatures. You have to run at three 17 temperatures to do the Arrhenius calculations.</p> <p>18 MR. HUTCHINSON: We can take a quick 19 break.</p> <p>20 THE VIDEOGRAPHER: We are now off 21 the video record. The time is 10:01 a.m.</p> <p>22 (Recess.)</p> <p>23 THE VIDEOGRAPHER: We are back on 24 the video record with Tape Number 2. The</p>	<p style="text-align: right;">Page 65</p> <p>1 selecting material, so they just asked me to 2 recommend a material for a certain application. And 3 I considered polypropylene and ruled it out, just 4 didn't have the right properties for the 5 application.</p> <p>6 Q. Doctor, have you ever selected a polymer 7 that has a lifetime warranty?</p> <p>8 MR. JACKSON: Objection, form.</p> <p>9 A. I don't believe so.</p> <p>10 BY MR. HUTCHINSON:</p> <p>11 Q. Doctor, would you ever guarantee to the 12 recipients of these medical devices that you 13 consulted for, would you ever guarantee to them that 14 their material would never oxidize?</p> <p>15 MR. JACKSON: Objection, form.</p> <p>16 A. No.</p> <p>17 BY MR. HUTCHINSON:</p> <p>18 Q. Doctor, on Page 3 of your expert report, 19 you reference ISOT. That stands for incipient 20 surface oxidation time; is that correct?</p> <p>21 A. Yes.</p> <p>22 Q. Is ISOT in any ASTM standard?</p> <p>23 A. It is nowhere. That is my own acronym.</p> <p>24 Q. Doctor, you didn't use a publication to</p>

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<p>1 come up with your own acronym, did you?</p> <p>2 A. I did not.</p> <p>3 Q. You made it up just for this experiment,</p> <p>4 didn't you?</p> <p>5 MR. JACKSON: Objection, form.</p> <p>6 A. No.</p> <p>7 BY MR. HUTCHINSON:</p> <p>8 Q. Where did you come up with your own</p> <p>9 acronym?</p> <p>10 MR. JACKSON: Objection, form.</p> <p>11 A. As I say, I have been using OIT testing</p> <p>12 for years.</p> <p>13 BY MR. HUTCHINSON:</p> <p>14 Q. I want to talk about ISOT.</p> <p>15 A. Yes, I know. And as part of that, I look</p> <p>16 at the shape of the OIT curve because normally it is</p> <p>17 a nice, smooth transition with two slopes and when</p> <p>18 you get the baseline meandering around and doing</p> <p>19 strange things, you know that there's something</p> <p>20 going on that's not normal. And so I always, just</p> <p>21 for my own thought processes, identify the point to</p> <p>22 where something chemically starts to happen and I</p> <p>23 call that the incipient oxidation point.</p> <p>24 Q. But that's something you made up?</p>	<p>1 A. Are you talking about in the human body?</p> <p>2 BY MR. HUTCHINSON:</p> <p>3 Q. Yes, sir.</p> <p>4 A. Hydrogen peroxide, there's all sorts of</p> <p>5 oxidizing agents.</p> <p>6 Q. All right, hydrogen peroxide. What else?</p> <p>7 A. Again, I'm not a medical doctor or a</p> <p>8 pathologist, but I have read many reports that refer</p> <p>9 to oxidizing agents being present in the body,</p> <p>10 especially with foreign body reactions. The body</p> <p>11 will generate oxidizing species.</p> <p>12 Q. Those are called reactive oxygen species,</p> <p>13 correct?</p> <p>14 A. Right, ROS.</p> <p>15 Q. My question to you is, though, can you</p> <p>16 name the oxidizing agents that you are aware of in</p> <p>17 the human body?</p> <p>18 MR. JACKSON: Objection, asked and</p> <p>19 answered.</p> <p>20 A. I just named one, hydrogen peroxide.</p> <p>21 BY MR. HUTCHINSON:</p> <p>22 Q. Can you name any others?</p> <p>23 MR. JACKSON: Objection, asked and</p> <p>24 answered.</p>
<p style="text-align: right; padding-right: 10px;">Page 67</p> <p>1 A. I did, yes.</p> <p>2 Q. Doctor, if you look at Page 5, it states,</p> <p>3 polypropylene is subject to degradation or weakening</p> <p>4 by oxidative agents.</p> <p>5 A. Where are you at now?</p> <p>6 Q. Page 5.</p> <p>7 MR. JACKSON: Chad, can you let us</p> <p>8 know which paragraph you are on?</p> <p>9 MR. HUTCHINSON: Yes, I'm sorry.</p> <p>10 Second paragraph, second sentence.</p> <p>11 THE WITNESS: Okay.</p> <p>12 BY MR. HUTCHINSON:</p> <p>13 Q. It states, the "chemical reactions</p> <p>14 continue to occur so long as any oxidizing agents,</p> <p>15 such as those present in the human body, are</p> <p>16 present." Do you see that?</p> <p>17 A. Yes.</p> <p>18 Q. Doctor, what are the names of the</p> <p>19 oxidizing agents?</p> <p>20 MR. JACKSON: Objection, form.</p> <p>21 A. Excuse me?</p> <p>22 Q. What are the names of the oxidizing agents</p> <p>23 that you reference here?</p> <p>24 MR. JACKSON: Objection, form.</p>	<p style="text-align: right; padding-right: 10px;">Page 69</p> <p>1 A. There's all sorts of peroxidases which are</p> <p>2 oxidative enzymes.</p> <p>3 BY MR. HUTCHINSON:</p> <p>4 Q. Other than hydrogen peroxide and enzymes,</p> <p>5 can you name any other type of oxidizing agents?</p> <p>6 MR. JACKSON: Objection, misstates</p> <p>7 witness testimony.</p> <p>8 A. Oxygen.</p> <p>9 BY MR. HUTCHINSON:</p> <p>10 Q. Anything else?</p> <p>11 A. That's all I can recall at this point.</p> <p>12 Q. Doctor, do you know the amount of hydrogen</p> <p>13 peroxide that's secreted in the body?</p> <p>14 MR. JACKSON: Objection, form.</p> <p>15 A. No.</p> <p>16 BY MR. HUTCHINSON:</p> <p>17 Q. Can you quantify it?</p> <p>18 MR. JACKSON: Objection.</p> <p>19 A. I cannot.</p> <p>20 BY MR. HUTCHINSON:</p> <p>21 Q. Have you ever attempted to quantify it?</p> <p>22 A. No.</p> <p>23 Q. Have you ever used any type of</p> <p>24 concentration of hydrogen peroxide to determine how</p>

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<p style="text-align: right;">Page 70</p> <p>1 it affects Prolene?</p> <p>2 A. I have not done that.</p> <p>3 Q. Doctor, do you have any idea how many or 4 what type of -- strike that.</p> <p>5 Do you have any idea of the amount of 6 enzymes, oxidizing enzymes that are secreted from 7 the body?</p> <p>8 MR. JACKSON: Objection, form.</p> <p>9 A. I have never measured it, no.</p> <p>10 BY MR. HUTCHINSON:</p> <p>11 Q. To your knowledge, has it ever been 12 quantified?</p> <p>13 A. I do not know.</p> <p>14 Q. Doctor, sitting here today, can you 15 quantify the amount of oxidizing agents that are 16 produced by the human body?</p> <p>17 MR. JACKSON: Objection, asked and 18 answered.</p> <p>19 A. Are you asking have I done it or could it 20 be done?</p> <p>21 BY MR. HUTCHINSON:</p> <p>22 Q. I am asking, have you done it?</p> <p>23 A. I have not done it.</p> <p>24 Q. Do you know the amount of oxidizing agents</p>	<p style="text-align: right;">Page 72</p> <p>1 A. Absolutely.</p> <p>2 BY MR. HUTCHINSON:</p> <p>3 Q. Doctor, do you have any idea how the 4 concentration level of hydrogen peroxide found 5 naturally in the body compares to 30 percent of 6 hydrogen peroxide?</p> <p>7 MR. JACKSON: Objection, form.</p> <p>8 A. I do not.</p> <p>9 BY MR. HUTCHINSON:</p> <p>10 Q. You would expect 30 percent hydrogen 11 peroxide to be much stronger than the amount of 12 peroxide found in the body, correct?</p> <p>13 MR. JACKSON: Objection, form.</p> <p>14 A. Absolutely, yes.</p> <p>15 (Priddy Deposition Exhibit 7 was 16 marked for identification.)</p> <p>17 BY MR. HUTCHINSON:</p> <p>18 Q. Doctor, I will hand you what's been marked 19 as Exhibit 7 to your deposition. Doctor, this is a 20 memo from Ethicon dated November 5, 1984. Do you 21 see that?</p> <p>22 (Witness reviewing document.)</p> <p>23 A. I do.</p> <p>24 Q. If you look with me, please, and by the</p>
<p style="text-align: right;">Page 71</p> <p>1 produced by the human body?</p> <p>2 MR. JACKSON: Objection, asked and 3 answered.</p> <p>4 A. No.</p> <p>5 BY MR. HUTCHINSON:</p> <p>6 Q. Doctor, do you have any opinions regarding 7 the quantity of oxidizing agents it would take to 8 oxidize Prolene?</p> <p>9 A. Well, Prolene is an oxidizable material, 10 so any oxidant is capable of oxidizing Prolene.</p> <p>11 Q. My question, sir: Do you have any idea 12 about the concentration level of oxidizing agents 13 that it would take to oxidize Prolene?</p> <p>14 A. Any detectable, measurable amount of an 15 oxidizing species is capable of oxidizing Prolene.</p> <p>16 Q. Can you quantify that, Doctor?</p> <p>17 MR. JACKSON: Objection, form.</p> <p>18 A. A detectable, I don't know what the 19 detection limit of a test you want to use, but if it 20 is detectable, it is capable of oxidizing Prolene.</p> <p>21 BY MR. HUTCHINSON:</p> <p>22 Q. What about a micromole, can a micromole 23 oxidize Prolene?</p> <p>24 MR. JACKSON: Objection, form.</p>	<p style="text-align: right;">Page 73</p> <p>1 way, this is a document that you reviewed or relied 2 on in reaching your opinions?</p> <p>3 A. I have, yes.</p> <p>4 Q. If you look with me on Page 3 at the 5 top --</p> <p>6 MR. JACKSON: Chad, can you give us 7 the Bates number of the page you are on?</p> <p>8 MR. HUTCHINSON: Yes, it's 15958454.</p> <p>9 MR. JACKSON: Thank you.</p> <p>10 BY MR. HUTCHINSON:</p> <p>11 Q. Top paragraph, middle sentence, it says, 12 "Immersion, with Peroxide Changes."</p> <p>13 Do you see that?</p> <p>14 A. Yes.</p> <p>15 Q. "To ensure strength of Prolene sutures, in 16 30 percent hydrogen peroxide after a year's time at 17 room temperature do not produce visible surface 18 cracks on any of the fibers."</p> <p>19 Do you see that?</p> <p>20 A. I do.</p> <p>21 Q. Doctor, do you have any reason to disagree 22 with this statement?</p> <p>23 A. No.</p> <p>24 Q. This shows that Prolene exposed to</p>

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<p style="text-align: right;">Page 74</p> <p>1 30 percent hydrogen peroxide for a year did not 2 produce visible surface cracks; is that correct? 3 A. That's what that's saying, yes. 4 Q. Doctor, how did you account for that when 5 reaching your opinions in this case? 6 A. Irrelevant. 7 Q. Why? 8 A. Because they didn't do anything to 9 determine whether the material had oxidized or not. 10 Q. Doctor, how do you know that? 11 A. I don't see the data where they detected 12 whether or not oxidation had actually, degradation 13 of the material had occurred. They just looked for 14 surface cracks. 15 Q. Doctor, surface cracks are a form of 16 degradation, are they not? 17 A. Yes. 18 Q. In fact, visible surface cracks are a form 19 of oxidation via degradation, correct? 20 A. Yes. 21 Q. Doctor, what is a Bakelite cap? 22 A. A Bakelite what? 23 Q. Spelled B-A-K-E-L-I-T-E, do you know what 24 a Bakelite cap is on a glass vial?</p>	<p style="text-align: right;">Page 76</p> <p>1 Do you see that? 2 A. Yes. 3 Q. Doctor, have you tested that opinion? 4 MR. JACKSON: Objection, form. 5 A. That is basic polymer chemistry 101. 6 BY MR. HUTCHINSON: 7 Q. My question is: Have you tested that 8 opinion? 9 MR. JACKSON: Objection, form. 10 A. Yes. 11 BY MR. HUTCHINSON: 12 Q. Are the test results included in your 13 expert report? 14 A. No. 15 Q. Doctor, what is the rate that chemicals 16 extract the antioxidant stabilizers? 17 MR. JACKSON: Objection, form. 18 A. It is dependent upon conditions. 19 BY MR. HUTCHINSON: 20 Q. What about conditions in vivo, what is the 21 rate that conditions in vivo extract Santonox R or 22 DLTDP? 23 A. That will be dependent upon a lot of 24 variables.</p>
<p style="text-align: right;">Page 75</p> <p>1 MR. JACKSON: Objection, form. 2 A. Yes. 3 BY MR. HUTCHINSON: 4 Q. What are Bakelite caps generally made of? 5 A. Bakelite, which is a phenolic resin. 6 Q. Doctor, can you explain why the hydrogen 7 peroxide ate away the Bakelite cap and did not 8 affect the Prolene? 9 A. Yes. 10 Q. How so? 11 A. Bakelite is a very hydrophilic, 12 water-loving, resin because phenolics are 13 hydroxylated materials which are hydrophylic. 14 Polypropylene is very hydrophobic, water-hating, so 15 polypropylene repulses and does not absorb water, 16 whereas Bakelite does absorb water. So the water, 17 the hydrogen peroxide would penetrate into the 18 Bakelite and allow chemical oxidation to occur. 19 Q. Let's look at Page 5 of your expert 20 report, Doctor. 21 A. Page 5, okay. 22 Q. Bottom paragraph, about the middle of the 23 paragraph. It states, "These chemicals act to 24 extract the antioxidant stabilizers."</p>	<p style="text-align: right;">Page 77</p> <p>1 Q. Doctor, can you sit here today and 2 quantify that rate of extraction? 3 MR. JACKSON: Objection. 4 A. No. 5 BY MR. HUTCHINSON: 6 Q. Doctor, can you explain to us in chemical 7 terms how blood extracts antioxidant stabilizers? 8 A. You mean scientifically how? 9 Q. Yes, sir. 10 A. Blood contains water plus a lot of other 11 things, it contains triglycerides, lipids, different 12 things. And it is the oil or the hydrophobic 13 components in blood, the fats, the oils, the lipids, 14 that extract the stabilizers from the plastic, and 15 even Dr., it starts with B, the Ethicon guy that did 16 the FTIR work, he measured the level of dilauryl 17 thiodipropionate in the surface of sutures that had 18 been removed and saw that there was no detectable, 19 it was all extracted out of the surface. So even 20 Ethicon knows that these antioxidants are 21 extractable from the material. 22 Q. Doctor, do you know what formalin is? 23 A. Yes. 24 Q. You understand that formalin contains</p>

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<p>1 formaldehyde?</p> <p>2 A. Yes.</p> <p>3 Q. Is formaldehyde a solvent?</p> <p>4 A. It is normally 37 percent concentration of</p> <p>5 water, but is it a solvent? Not really.</p> <p>6 Q. Would you consider formalin to be a</p> <p>7 solvent?</p> <p>8 A. Formalin is 37 percent formaldehyde and</p> <p>9 water. Water is a terrible solvent. It is not</p> <p>10 going to extract anything of consequence from</p> <p>11 polypropylene. Polypropylene is repulsive to water.</p> <p>12 Q. But my question, sir: Is formalin a</p> <p>13 solvent?</p> <p>14 A. It is a solvent for ionic species, but it</p> <p>15 is not a solvent for like additives.</p> <p>16 Q. Doctor, would you be able to draw out the</p> <p>17 chemical structure for the reaction between blood</p> <p>18 and Santonox R?</p> <p>19 MR. JACKSON: Objection, form.</p> <p>20 A. The Santonox R does not react with blood,</p> <p>21 it reacts with oxidizing species that would be</p> <p>22 in the blood.</p> <p>23 BY MR. HUTCHINSON:</p> <p>24 Q. Doctor, if we turn to Page 7 of your</p>	<p>1 A. That's correct.</p> <p>2 Q. And a free radical is -- strike that.</p> <p>3 There is no difference between a free</p> <p>4 radical formed in the body or a free radical formed</p> <p>5 during the heat extrusion process, correct?</p> <p>6 MR. JACKSON: Objection, form.</p> <p>7 A. In the sense they are both free radicals.</p> <p>8 BY MR. HUTCHINSON:</p> <p>9 Q. In fact, Santonox R and DLTDP are free</p> <p>10 radical scavengers, aren't they?</p> <p>11 A. DLTDP is not a free radical scavenger,</p> <p>12 Santonox R is a free radical scavenger.</p> <p>13 Q. Why do you say DLTDP is not a free radical</p> <p>14 scavenger?</p> <p>15 A. Because it works by a different mechanism.</p> <p>16 What it does is the sulfur reacts with oxygen</p> <p>17 species.</p> <p>18 It doesn't have to be a free radical</p> <p>19 oxygen, it can just be oxygen, specifically</p> <p>20 hydroperoxides, to become a higher, either a sulfone</p> <p>21 or a sulfoxide which is a higher oxidized form. The</p> <p>22 sulfur converts the hydroperoxide group to an</p> <p>23 alcohol. But that's a different chemistry. That's</p> <p>24 not free radical-based.</p>
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<p>1 expert report, top paragraph, last sentence, you</p> <p>2 reference antioxidant Santonox R that interferes</p> <p>3 with the oxidative chain reaction.</p> <p>4 A. Yes.</p> <p>5 Q. Is that correct?</p> <p>6 A. Yes.</p> <p>7 Q. Doctor, we talked about ROS earlier, just</p> <p>8 a minute ago, correct?</p> <p>9 MR. JACKSON: Objection, form.</p> <p>10 A. Yes.</p> <p>11 BY MR. HUTCHINSON:</p> <p>12 Q. And that stands for reactive oxygen</p> <p>13 species?</p> <p>14 A. Correct.</p> <p>15 Q. And reactive oxygen species, they possess</p> <p>16 a free radical, don't they?</p> <p>17 MR. JACKSON: Objection, form.</p> <p>18 A. They can, yes.</p> <p>19 BY MR. HUTCHINSON:</p> <p>20 Q. And a reactive oxygen species has a</p> <p>21 non-bonded electron that wants to bond with</p> <p>22 something, doesn't it?</p> <p>23 A. The ones that are free radicals, yes.</p> <p>24 Q. And a free radical is not bonded, is it?</p>	<p>1 Q. Let's talk about the chemistry for</p> <p>2 Santonox R.</p> <p>3 MR. JACKSON: Chad, he wasn't</p> <p>4 through answering his question. You got</p> <p>5 to let him finish.</p> <p>6 BY MR. HUTCHINSON:</p> <p>7 Q. Santonox R is designed to remove free</p> <p>8 radicals when they are formed, correct?</p> <p>9 A. I wouldn't say remove, but negate the</p> <p>10 effects of free -- interferes with free radical</p> <p>11 chain reactions.</p> <p>12 Q. Doctor, let's look at Page 8 at the top.</p> <p>13 You reference the testing you did, the gas</p> <p>14 chromatography, mass spectroscopy, did I say that --</p> <p>15 A. That's correct.</p> <p>16 Q. Is that the testing that you did?</p> <p>17 A. Yes.</p> <p>18 Q. Did you personally do the GS-MC testing?</p> <p>19 A. GC-MS.</p> <p>20 Q. GC-MS testing?</p> <p>21 A. I don't run lab equipment. Trained</p> <p>22 technicians run lab equipment. I worked with a</p> <p>23 technician to tell him how I wanted the test</p> <p>24 performed, yes.</p>

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<p style="text-align: right;">Page 82</p> <p>1 Q. Who did the GC-MS testing, Doctor?      2 A. Steve Johnson.      3 Q. He did it too?      4 A. Yes, he is the technician that does GC-MS      5 and the OIT test.      6 Q. Which did Steve Johnson do first, did he      7 do the GC-MS or the DSC testing?      8 MR. JACKSON: Objection, form.      9 A. He did the OIT first and then I wanted to      10 see if it correlated with the additives so I asked      11 him to do GC-MS so I could see if there was a      12 statistical correlation.      13 BY MR. HUTCHINSON:      14 Q. Let's talk about the GC-MS testing that      15 Steve Johnson did. Did Steve Johnson's GC-MS      16 experiment follow any standard or published      17 procedure?      18 A. It followed what's called SOP, standard      19 operating procedure. Again, all certified      20 laboratories need SOPs for everything they do.      21 Those SOPs are audited annually, and he followed      22 his SOP for GC-MS.      23 Q. Which SOP did Mr. Johnson follow?      24 A. The one for GC-MS in the lab.</p>	<p style="text-align: right;">Page 84</p> <p>1 A. No, I did not.      2 Q. Doctor, did Steve Johnson perform any      3 controls in his GC-MS experiment?      4 A. Yes.      5 Q. What were they?      6 A. He always puts in an internal standard in      7 the solvent that he extracts, the additives from the      8 plastic, and that internal standard he looks at the      9 size of the response and the retention time to make      10 sure that the equipment is operating. In other      11 words, it is a known material spiked into the      12 solvent and if that peak is not right, he knows      13 there's an issue.      14 Q. Did that generate data?      15 MR. JACKSON: Chad, you have to let      16 the witness finish his answer.      17 BY MR. HUTCHINSON:      18 Q. I'm sorry, Doctor, if I interrupted you.      19 Did that generate data?      20 A. What do you mean?      21 Q. Using the control, when Mr. Johnson used      22 the control, did it generate any data?      23 A. Yes.      24 Q. Where is that data?</p>
<p style="text-align: right;">Page 83</p> <p>1 Q. But what number?      2 A. I don't -- it's probably in the lab report      3 he sent me, but I don't have the number memorized.      4 Q. Doctor, did you ever touch the GC-MS      5 equipment?      6 MR. JACKSON: Objection, form.      7 A. No.      8 BY MR. HUTCHINSON:      9 Q. Did you ever touch the DSC equipment?      10 MR. JACKSON: Objection, form.      11 A. No.      12 BY MR. HUTCHINSON:      13 Q. Have you ever even seen the GC-MS or DSC      14 equipment?      15 MR. JACKSON: Objection, form.      16 A. Yes, I have.      17 BY MR. HUTCHINSON:      18 Q. At Steve Johnson's lab?      19 A. At Steve Johnson's lab. As a matter of      20 fact I have watched him in the past run it.      21 Q. But you didn't watch him do this      22 experiment --      23 A. No.      24 Q. -- that we are here about today?</p>	<p style="text-align: right;">Page 85</p> <p>1 A. It would be in his GC-MS data report.      2 Q. Is Mr. Johnson's GC-MS data report      3 included on the flash drive that you gave me before      4 the deposition?      5 A. I believe so.      6 Q. Why wasn't that GC-MS data included in      7 your expert report?      8 A. I included just this comment of the      9 correlation, but I did not include the data in the      10 report.      11 Q. But why not? Why didn't you include the      12 data in your report?      13 A. I just didn't.      14 Q. Doctor, did Steve Johnson ever try to      15 measure the concentration level of DLTDTP?      16 A. Yes.      17 Q. What was the result of the concentration      18 level of DLTDTP?      19 A. When he ran the test, he did not see the      20 DLTDTP. He couldn't detect it.      21 Q. Doctor, have you personally ever tried to      22 measure the concentration level of DLTDTP in Prolene?      23 A. Through Steve Johnson I have attempted to      24 do it.</p>

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<p style="text-align: right;">Page 86</p> <p>1 Q. But you personally? 2 MR. JACKSON: Objection, asked and 3 answered. 4 A. I have not run the equipment, no. 5 BY MR. HUTCHINSON: 6 Q. Doctor, are you aware of any studies that 7 show DLTDP is lost from Prolene once it is implanted 8 in vivo? 9 A. Yes. 10 Q. What's the name of the study? 11 A. That was done by Dr. Burkley, I think his 12 name was. 13 Q. You are talking about an internal Ethicon 14 scientist? 15 A. Yes. 16 Q. Doctor, are you aware of any published 17 peer-reviewed literature that shows DLTDP is lost 18 from Prolene in vivo? 19 A. Just Dr. Burkley's work. 20 Q. And nothing else, correct? 21 A. That's correct. 22 Q. Doctor, have you ever read Dr. Howard 23 Jordi's expert reports? 24 A. I don't recall.</p>	<p style="text-align: right;">Page 88</p> <p>1 MR. JACKSON: Objection, form. 2 A. That's correct, yes. 3 BY MR. HUTCHINSON: 4 Q. Doctor, did you do any type of appropriate 5 testing to determine the level of DLTDP in Prolene? 6 MR. JACKSON: Objection, form. 7 A. Yes, I tried to. I actually had him 8 experiment with different conditions to try to 9 detect the DLTDP. He did find a condition where he 10 was able to see it. It's just not -- so it's there, 11 it's just not reported in this data. 12 Q. What test did he use to detect DLTDP? 13 A. GC-MS, again. It's just he ran it under 14 different conditions. 15 Q. Doctor, why is that information not in 16 your expert report? 17 A. Because the purpose for doing it was to 18 just make sure that it was there. I wanted to make 19 sure it was there. 20 Q. And you confirmed it was there? 21 A. I confirmed it was there. 22 Q. Or rather Mr. Johnson confirmed it was 23 there? 24 MR. JACKSON: Objection, form.</p>
<p style="text-align: right;">Page 87</p> <p>1 Q. Do you know Dr. Howard Jordi? 2 A. I know there's a Jordi Lab. 3 Q. Do you know if the Jordi Labs ever 4 detected DLTDP in Prolene? 5 A. I don't know. 6 Q. If Dr. Jordi's lab did detect DLTDP in 7 Prolene, that would be inconsistent with the results 8 of your tests, correct? 9 MR. JACKSON: Objection, form. 10 A. No. 11 BY MR. HUTCHINSON: 12 Q. I thought you told me your tests did not 13 detect DLTDP. 14 A. No, I'm saying that the way the test was 15 run, it did not detect it. He only saw a peak for 16 the Santonox R. 17 Q. Doctor, is it your testimony under oath 18 that the Prolene sample that Mr. Johnson used did 19 not have any DLTDP in it? 20 A. No, it likely did. It's just the way 21 that particular test was run, it was 22 non-detectable. But -- yeah, that's all. 23 Q. It probably wasn't the best test to 24 determine whether or not DLTDP was in the Prolene?</p>	<p style="text-align: right;">Page 89</p> <p>1 A. Yes. 2 BY MR. HUTCHINSON: 3 Q. Doctor, let's go back to the GC-MS test. 4 Did you determine the weight loss for Santonox R 5 before Steve Johnson did his testing? 6 A. Weight loss? 7 Q. The weight loss rate? 8 A. I don't understand the question. You mean 9 by TGA? 10 Q. Yes, by glass transition, correct. 11 A. No, TGA is thermogravimetric analysis. 12 It measures weight loss of materials versus 13 temperature. 14 Q. TGA? 15 A. TGA. 16 Q. Did you do any type of TGA analysis to 17 determine the weight loss for DLTDP? 18 A. No. 19 Q. Did you do any type of TGA analysis to 20 determine the weight loss of Santonox R? 21 A. No. 22 Q. Why not? 23 A. As I say, the only time I was looking for 24 volatility, if you will, in other words, loss during</p>

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<p style="text-align: right;">Page 90</p> <p>1 the heat process, was by retention time and the gas 2 chromatograph which gives me a feel for volatility. 3 Q. Doctor, do you know what the recommended 4 ranges are for DLTDP and Santonox R by weight? 5 MR. JACKSON: Objection, form. 6 A. I mean, that's application-specific. I 7 know what the formulation for Prolene, has a target 8 range of weight. 9 BY MR. HUTCHINSON: 10 Q. Do you know what the target range of 11 weight of DLTDP and Santonox R is for Prolene? 12 A. I have seen it. It seems like it was 13 between 2,000 and 4,000 parts per million or .2 to 14 .4 percent, I think, in that range. It's probably 15 not correct, but in that ballpark. 16 Q. Doctor, do you know what the weight loss 17 rate is for DLTDP? 18 A. From Prolene? 19 Q. Yes. 20 A. Under what conditions? 21 Q. In vivo. 22 A. In vivo, again, the only data point I got 23 is Dr. Burkley's data where he saw it was totally 24 depleted from the surface after a period of time in</p>	<p style="text-align: right;">Page 92</p> <p>1 ramped up over time because these additives, like 2 if the oven temperature was set at 40 degrees and 3 you injected the sample, the additive would never 4 come through the instruments. So you've got to keep 5 raising the temperature until it comes through. 6 Q. What temperature was it when the material 7 began coming through? 8 MR. JACKSON: Objection, form. 9 A. I can't tell you precisely. I can tell 10 you it was over 200 degrees. 11 BY MR. HUTCHINSON: 12 Q. Was a solvent used by Mr. Johnson with 13 this GC-MS? 14 A. Yes. 15 Q. Do you know what type of solvent Mr. 16 Johnson used? 17 A. Methylene chloride. 18 Q. Do you know what quantity of methylene 19 chloride that Mr. Johnson used? 20 A. Again, it is in his lab procedure he sent 21 me. I don't know the number offhand. 22 Q. Doctor, you will agree that that solvent 23 only extracts volatile materials, correct? 24 MR. JACKSON: Objection, form.</p>
<p style="text-align: right;">Page 91</p> <p>1 vivo. 2 Q. Doctor, do you know what the weight loss 3 rate is for DLTDP in vivo? 4 A. That's what I just answered. The only 5 thing I know is from Dr. Burkley's work. 6 Q. Same question for Santonox R: Do you know 7 what the weight loss rate is for Santonox R in vivo? 8 A. No. 9 Q. Doctor, do you know what the melting point 10 is for DLTDP? 11 A. Not offhand. 12 Q. Do you know what the melting point for 13 Santonox R is? 14 A. Again, not offhand. 15 Q. Doctor, when we talk about the GC-MS 16 testing, what color was the exemplar that Steve 17 Johnson tested? 18 A. It's in the lab report he sent me. He 19 listed the lot number and the color. 20 Q. What color was it? 21 A. I don't recall if it was blue or white. 22 I'd have to look at the lab report. 23 Q. What temperature was the GC-MS set for? 24 A. It's a program. Its oven temperature is</p>	<p style="text-align: right;">Page 93</p> <p>1 A. No. 2 BY MR. HUTCHINSON: 3 Q. Does it extract volatile materials? 4 A. Yes. 5 Q. Doctor, did you know -- my understanding 6 in reading your report is that the GC-MS test only 7 found Santonox R; is that right? 8 A. That's the only stabilizer that it saw, 9 that he identified as a stabilizer. 10 Q. Did it pick up any other type of additives 11 to the Prolene? 12 MR. JACKSON: Objection, form. 13 A. I do not believe so. 14 BY MR. HUTCHINSON: 15 Q. Doctor, did the GC-MS that Mr. Johnson 16 did, did it detect Procol LA-10? 17 A. No. 18 Q. Why not? 19 A. It was probably not volatile enough to 20 make it through the instrument. 21 Q. Do you know what the flash point is for 22 Procol LA-10? 23 A. Not offhand, no. 24 Q. Do you know the melting point?</p>

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<p>1 A. No.</p> <p>2 Q. Do you know the flash point for Santonox</p> <p>3 R?</p> <p>4 A. No.</p> <p>5 Q. Do you know the flash point for DLTDP?</p> <p>6 A. I do not.</p> <p>7 Q. Do you know the flash point or melting</p> <p>8 point for calcium stearate?</p> <p>9 A. No.</p> <p>10 Q. Do you have any idea why Mr. Johnson's</p> <p>11 GC-MS test did not detect calcium stearate?</p> <p>12 A. Yes.</p> <p>13 Q. Why?</p> <p>14 A. It wouldn't be soluble in methylene</p> <p>15 chloride. It's only going to extract out what's</p> <p>16 soluble in that solvent.</p> <p>17 Q. Did the GCMS test detect any blue pigment?</p> <p>18 A. No.</p> <p>19 Q. Why not?</p> <p>20 A. Either it's not soluble in methylene</p> <p>21 chloride or its boiling point is too high to make</p> <p>22 it through the gas chromatograph, one of the two.</p> <p>23 Q. Do you know what the boiling point is of</p> <p>24 the CPC blue pigment?</p>	<p>1 marked for identification.)</p> <p>2 BY MR. HUTCHINSON:</p> <p>3 Q. Doctor, I want to hand you what we'll mark</p> <p>4 as Exhibit 8 to your deposition.</p> <p>5 (Witness reviewing document.)</p> <p>6 Q. Exhibit 8 is for an antioxidant DLTDP, do</p> <p>7 you see that?</p> <p>8 A. I do.</p> <p>9 Q. The flash point for DLTDP is 150 degrees</p> <p>10 C; is that correct?</p> <p>11 A. That's what it says, yes.</p> <p>12 Q. And Doctor, do you have any reason to</p> <p>13 believe that the flash point for DLTDP would be</p> <p>14 significantly different than 150 degrees C?</p> <p>15 A. No. It sounds low but I don't have any</p> <p>16 reason to dispute it.</p> <p>17 Q. Doctor, a sample of mesh heated to</p> <p>18 200 degrees C is 50 degrees Celsius hotter than the</p> <p>19 flash point for DLTDP, isn't it?</p> <p>20 A. That's correct.</p> <p>21 Q. Doctor, that would volatize DLTDP,</p> <p>22 wouldn't it?</p> <p>23 A. No.</p> <p>24 Q. Why not?</p>
<p>1 A. I do not.</p> <p>2 Q. Doctor, did you ever do any type of FTIR</p> <p>3 analyses on Prolene?</p> <p>4 A. No.</p> <p>5 Q. Did Mr. Johnson to your knowledge do any</p> <p>6 type of FTIR analyses on Prolene?</p> <p>7 A. No.</p> <p>8 Q. Doctor, let's look at Page 12 of your</p> <p>9 expert report. Are you there with me?</p> <p>10 A. I am.</p> <p>11 Q. It states, "The mesh sample," in the top</p> <p>12 of the first paragraph.</p> <p>13 A. Yes.</p> <p>14 Q. "The mesh sample is heated to 200 degrees</p> <p>15 C under pure nitrogen."</p> <p>16 Is that right?</p> <p>17 A. Yes.</p> <p>18 Q. Doctor, do you know, we talked about this</p> <p>19 earlier, do you have any idea what the flash point</p> <p>20 is for DLTDP?</p> <p>21 MR. JACKSON: Objection, asked and</p> <p>22 answered.</p> <p>23 A. No.</p> <p>24 (Priddy Deposition Exhibit 8 was</p>	<p>1 A. Flash point has nothing to do with boiling</p> <p>2 point.</p> <p>3 Q. A flash point is the temperature at which</p> <p>4 an organic compound gives off enough vapor to ignite</p> <p>5 in air; is that right?</p> <p>6 A. It's ignitable in air by a spark, yes.</p> <p>7 MR. JACKSON: Chad, I am going to</p> <p>8 object to the use of this document just</p> <p>9 on foundation. I don't know what it is.</p> <p>10 BY MR. HUTCHINSON:</p> <p>11 Q. Doctor, what did you do to ensure that</p> <p>12 DLTDP or Santonox R were not burned off when Mr.</p> <p>13 Johnson heated the mesh to 200 degrees C?</p> <p>14 A. As I explained to you, I had him determine</p> <p>15 its retention time in the GC which gave me a feel</p> <p>16 for its level of volatility and based upon that</p> <p>17 data, I knew it was not a very volatile chemical.</p> <p>18 And of course when chemicals are embedded in a</p> <p>19 plastic, it's very difficult to drive them, vaporize</p> <p>20 them and get them out of the plastic at low levels.</p> <p>21 Q. Doctor, on Page 13 of your expert report</p> <p>22 under Section 11 it states, "The antioxidants,"</p> <p>23 plural, "present in the ten meshes were then</p> <p>24 extracted."</p>

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<p style="text-align: right;">Page 98</p> <p>1        Did I read that correctly?      2        A. That's correct.      3        Q. DLTDP was found as an antioxidant in this      4 case; is that correct?      5        MR. JACKSON: Objection, form.      6        A. Just a minute. Let me read through this      7 real quick.      8              (Witness reviewing document.)      9        A. Now, what's your question?      10 BY MR. HUTCHINSON:      11      Q. My question is, sir: Was DLTDP extracted      12 using the methylene chloride solvent?      13      A. All I can say is that in this particular      14 test referred to right here, it was not detected,      15 and I don't know exactly why it wasn't detected. I      16 don't know if it wasn't extracted or if the      17 conditions for the GC-MS analysis just were such      18 that it didn't detect it.      19      Q. Did you ever make any effort to find out      20 why?      21      MR. JACKSON: Objection, form.      22      A. I asked him to try to detect DLTDP and he      23 played around and was finally able to come up with      24 conditions that he could see it. But it was not</p>	<p style="text-align: right;">Page 100</p> <p>1        A. Okay.      2        Q. It states, "The polymer chain is      3 disentangled."      4        Do you see that?      5        A. Yes.      6        Q. Doctor, would you agree that      7 disentanglement of polymer chains allows a polymer      8 to elongate?      9        MR. JACKSON: Objection, form.      10      A. No.      11 BY MR. HUTCHINSON:      12      Q. Doctor, if polymers, if polymer chains do      13 not disentangle, would the polymer become brittle?      14      A. If the polymer chains do not disentangle,      15 would the polymer become brittle?      16      Q. Correct.      17      A. Yeah, it can, yes.      18      Q. But you disagree that disentanglement of      19 polymer chains allows a polymer to elongate?      20      MR. JACKSON: Objection, misstates      21 witness testimony.      22      A. A polymer will elongate under stress      23 whether or not it is entangled. So I guess I'm      24 not --</p>
<p style="text-align: right;">Page 99</p> <p>1        this particular test right here, he couldn't see it.      2 BY MR. HUTCHINSON:      3        Q. What concentration level did Mr. Johnson      4 find DLTDP in?      5        A. The particular -- I remember numbers,      6 hundreds of parts per million.      7        Q. Right, but can you quantify the amount of      8 DLTDP concentration level that Mr. Johnson found?      9        A. I'm sorry, the question again?      10      Q. Can you quantify the concentration level      11 of the DLTDP that Mr. Johnson found?      12      A. As I said, it was hundreds of parts per      13 million. I just don't remember the exact number.      14      Q. Did Mr. Johnson ever tell you that exact      15 number?      16      MR. JACKSON: Objection, form.      17      A. Yes.      18 BY MR. HUTCHINSON:      19      Q. Where would that data be included?      20      A. In the data report.      21      Q. Where is the data report?      22      A. Should be on the flash drive.      23      Q. Look at Page 9 for me, please, of your      24 expert report under Summary, Number 2.</p>	<p style="text-align: right;">Page 101</p> <p>1        BY MR. HUTCHINSON:      2        Q. Should the polymer chains become      3 disentangled for a polymer to elongate?      4        A. No.      5        Q. Doctor, when you reviewed the internal      6 documents from Ethicon, did you review any documents      7 on biocompatibility?      8        MR. JACKSON: Objection, form.      9        Q. Doctor?      10      A. I'm thinking. I guess I'm not sure      11 specifically what you are referring to, but I would      12 say yes.      13      Q. Do you have any opinions about the      14 biocompatibility testing of Prolene that Ethicon      15 did?      16      A. I don't have an opinion on that.      17      Q. Doctor, have you ever designed pelvic      18 mesh?      19      MR. JACKSON: Objection, asked and      20 answered.      21      A. No.      22 BY MR. HUTCHINSON:      23      Q. Have you ever done any type of      24 biomechanical testing of pelvic mesh?</p>

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<p style="text-align: right;">Page 102</p> <p>1 A. The only testing I have done regarding 2 Prolene mesh are listed in my report. 3 Q. So we are clear, you have never done any 4 biomechanical testing of Prolene mesh, correct? 5 A. That's correct. 6 Q. You have never done any type of 7 biomechanical testing of Prolene, have you? 8 A. No. 9 Q. Have you ever been involved in any type of 10 clinical research regarding Prolene? 11 A. Other than reviewing a lot of documents on 12 the research, no. 13 Q. My question is, sir: Have you personally 14 ever been involved in any type of clinical research 15 regarding Prolene? 16 A. Not as far as conducting the research, no. 17 Q. Or mesh, have you ever been involved in 18 any clinical research regarding mesh? 19 MR. JACKSON: Objection, form. 20 A. Just reviewing the results of the studies, 21 that's it. 22 BY MR. HUTCHINSON: 23 Q. Have you ever tested a mesh explant? 24 MR. JACKSON: Objection, form.</p>	<p style="text-align: right;">Page 104</p> <p>1 A. It's got stabilizers and additives, yes. 2 BY MR. HUTCHINSON: 3 Q. Prolene and polypropylene are not 4 identical, are they? 5 A. Prolene is polypropylene with additives. 6 Q. And pure polypropylene is not identical to 7 Prolene, correct? 8 MR. JACKSON: Objection, asked and 9 answered. 10 BY MR. HUTCHINSON: 11 Q. Pure polypropylene? 12 A. Because pure, with no additives, is 13 different than a formulation with additives, yes. 14 Q. And Ethicon's product is a formulation 15 with additives, correct? 16 A. That's correct. All polypropylene 17 products contain additives. They have to. 18 Q. But they are different polymers? 19 A. Polymer is the same. 20 Q. Doctor, what medical products are you 21 designated to give opinions about? 22 A. You mean in legal cases? I've done 23 consulting. 24 Q. No, in the deposition that you are here</p>
<p style="text-align: right;">Page 103</p> <p>1 A. I served as a consultant on a project 2 several years ago involving Kugel mesh and at that 3 point I received a mesh sample, but I don't recall 4 actually evaluate -- or testing it. 5 BY MR. HUTCHINSON: 6 Q. Do you know what the chemical composition 7 is of the Kugel mesh? 8 A. Yes, it was a polyester. 9 Q. It wasn't Prolene, correct? 10 A. No. 11 Q. Doctor, you will agree that Prolene has a 12 chemical composition difference compared to 13 polypropylene? 14 A. Absolutely, yes. Compared to what? 15 Q. Compared to polypropylene. Polypropylene 16 and Prolene are chemically different, aren't they, 17 sir? 18 MR. JACKSON: Objection, form. 19 A. Prolene meshes are polypropylene. 20 BY MR. HUTCHINSON: 21 Q. Doctor, as a materials scientist, would 22 you agree that Prolene has a different chemical 23 composition compared to pure polypropylene? 24 MR. JACKSON: Objection, form.</p>	<p style="text-align: right;">Page 105</p> <p>1 for today, In Re Ethicon Pelvic Repair System 2 Products Liability Litigation. 3 MR. JACKSON: Objection, form. 4 A. I was asked to opine on the use of 5 polypropylene in the TTV and the Gynemesh product 6 lines for urinary incontinence and the pelvic 7 products. 8 BY MR. HUTCHINSON: 9 Q. Doctor, do you know the names of the 10 products that you are designated to give testimony 11 about for the plaintiffs? 12 A. As I said, the TTV products, there's like 13 four or five of those and then the prolapse 14 products, there are several of those. 15 Q. Do you know the names of those products? 16 A. Boy, I'm terrible at names. I don't 17 remember the details of all the names, no. I was 18 shown the names and have seen the names and, yes, 19 but I just don't recall all the names. 20 Q. Do the opinions that you are giving today 21 relate to all of these products? 22 A. If they contain polypropylene, yes. 23 Q. Doctor, have you ever seen a TTV -- strike 24 that.</p>

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<p style="text-align: right;">Page 106</p> <p>1 I am going to represent to you that you      2 are designated in cases involving Prolene Soft mesh,      3 Gynemesh PS, TVT, Prolift, TVT-O, Prolift+M, TVT      4 Exact, TVT Secur, Prosima and TVT Abbrevio?      5 A. I have seen all those names, yes.      6 Q. Thank you. Doctor, have you ever held any      7 of those devices in your hand?      8 MR. JACKSON: Objection, form.      9 A. Yes.      10 BY MR. HUTCHINSON:      11 Q. When?      12 A. Back in December when I received the      13 samples for lab testing.      14 Q. Did you receive one sample of each      15 product?      16 A. No, I received, I think, four of the      17 Gynemesh products and six of the TVT products.      18 Q. So fair to say you have never held Prosima      19 or Prolift or Prolift+M in your hands?      20 MR. JACKSON: Objection, form.      21 A. That's correct.      22 BY MR. HUTCHINSON:      23 Q. Doctor, do you know what the indications      24 are for those products?</p>	<p style="text-align: right;">Page 108</p> <p>1 those particular products?      2 A. Again, I've seen that information. I just      3 don't recall it.      4 Q. Do you know how many newtons of force are      5 placed on the mesh in vivo?      6 A. I do not.      7 Q. Doctor, what do you know about the      8 manufacturing process Ethicon uses to make Prolene?      9 MR. JACKSON: Objection, form.      10 A. I know that the resin is manufactured in      11 West Virginia and then it's converted to fiber in      12 Georgia, and then woven into mesh and sent over to      13 Europe where it's cut and then it's shipped back to      14 the US for sale.      15 Q. Doctor, is the mesh woven or knitted?      16 A. Oh, boy, I'm not sure of the semantics of      17 the difference between those to be able to answer.      18 Q. Doctor, do you know if Prolift+M, the mesh      19 in Prolift+M is made of a hundred percent Prolene?      20 A. I remember, when I looked through the data      21 in the data sheets, I remember that some of the      22 products have polypropylene plus another      23 biodegradable kind of material, either      24 polycaprolactone or glycolate biodegradable</p>
<p style="text-align: right;">Page 107</p> <p>1 A. Indications?      2 Q. Yes.      3 A. What do you mean by indications?      4 Q. What the product is indicated for from a      5 medical standpoint.      6 A. In general, yes.      7 Q. Doctor, do you know how long those      8 products have been on the market?      9 A. The years vary but it started back in the      10 1990s and then there's recent introductions as      11 recent as, I think 2010 or '11.      12 Q. Can you tell us the date that each of      13 those products were introduced to the market?      14 MR. JACKSON: Objection, form.      15 A. Again, I have seen the dates, I just don't      16 recall.      17 BY MR. HUTCHINSON:      18 Q. Do you know the physical dimensions of the      19 mesh of each of those products?      20 MR. JACKSON: Objection, form.      21 A. Again, I have seen pictures and photo-      22 graphs of them, but I don't recall exact dimensions.      23 BY MR. HUTCHINSON:      24 Q. Do you know the weight of the mesh of</p>	<p style="text-align: right;">Page 109</p> <p>1 material. So it is a hybrid system.      2 Q. Doctor, my question is: Do you know what      3 type of biodegradable material Prolift+M has in its      4 mesh?      5 MR. JACKSON: Objection, form.      6 A. I have seen it, I just don't recall.      7 BY MR. HUTCHINSON:      8 Q. Doctor, did you make any efforts to find      9 out what type of biodegradable material is in      10 Prolift+M?      11 A. Other than reading the sheets that      12 describe them, no.      13 Q. Do you consider yourself an expert in the      14 manufacturing process of pelvic mesh?      15 MR. JACKSON: Objection, form.      16 A. Just the manufacture as far as it goes to      17 making the fibers. Once the fibers are made, I'm      18 not an expert from that point on.      19 BY MR. HUTCHINSON:      20 Q. Doctor, have you ever invented any type of      21 polypropylene product that's turned into a fiber?      22 A. Invented a polypropylene product, I have      23 worked on polypropylene additive formulations. I      24 led a group at Dow for several years in the 1990s</p>

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<p style="text-align: right;">Page 110</p> <p>1 where we experimented with different Dow products 2 including polypropylene and the additives and 3 stabilizers that need to be added to those to make 4 various types of products including fibers. 5 Q. Doctor, have you personally ever performed 6 any testing to determine if Prolene degrades in 7 vivo? 8 A. I have not done any in vivo testing 9 myself, no. 10 Q. And you haven't done any loss of 11 mechanical property testing in vivo, have you? 12 A. I just reviewed the Ethicon documents 13 which showed the loss of strength properties from in 14 vivo implanted Prolene sutures. 15 Q. But you have never done any testing, have 16 you? 17 MR. JACKSON: Objection, form. 18 A. Just reviewed work of others, yes. 19 BY MR. HUTCHINSON: 20 Q. In fact, you have never tested the 21 durability of Prolene? 22 A. In vivo? 23 Q. Yes. 24 A. Not directly, no.</p>	<p style="text-align: right;">Page 112</p> <p>1 testing of Prolene, have you? 2 A. I sure reviewed the Ethicon documents on 3 the Young's modulus of Prolene. I was shocked by 4 what I saw. 5 Q. You have never done any testing of that, 6 have you? 7 A. I have done modulus testing. 8 Q. On Prolene? 9 A. Not on Prolene, no. 10 Q. You have had the resources available to do 11 all of this testing of Prolene, haven't you? 12 A. I've had it, but I had all those documents 13 which gave me the data that I needed to opine on 14 that issue. 15 Q. You will agree with me that degradation 16 affects the physical properties of the polymer? 17 A. Absolutely, yes. 18 Q. And it will affect the physical properties 19 of the mesh and/or suture, correct? 20 A. That's correct. 21 Q. You will agree that evaluation of the 22 physical properties of mesh is an important part in 23 your analysis on degradation, correct? 24 A. Absolutely, yes.</p>
<p style="text-align: right;">Page 111</p> <p>1 Q. Have you ever tested the durability of 2 Prolene in any form or fashion? 3 MR. JACKSON: Objection, form. 4 A. Well, yes, the OIT testing. 5 BY MR. HUTCHINSON: 6 Q. What about tensile strength, have you ever 7 tested tensile strength of Prolene, whether it be in 8 vivo or outside the body? 9 A. I just reviewed the Ethicon documents 10 which do that kind of testing. 11 Q. You have never done tensile strength 12 testing, have you? 13 A. I have done tensile strength testing. 14 Q. Of Prolene? 15 A. Not of Prolene, no. 16 Q. You have never done elongation testing of 17 Prolene, have you? 18 A. Just reviewed those documents. 19 Q. You have never done any toughness testing 20 of Prolene, have you? 21 MR. JACKSON: Objection, form. 22 A. No, just reviewed the documents. 23 BY MR. HUTCHINSON: 24 Q. You have never done any Young's modulus</p>	<p style="text-align: right;">Page 113</p> <p>1 Q. As well as oxidation? 2 MR. JACKSON: Objection, form. 3 A. Yes. 4 BY MR. HUTCHINSON: 5 Q. Doctor, have you ever done any type of 6 testing or analysis on an explanted Prolene mesh? 7 A. Just reviewed the literature and the 8 documents. 9 Q. But you have never done any actual testing 10 of an actual explanted Prolene mesh, have you? 11 A. Not myself, no. 12 Q. Have you ever seen a Prolene explanted 13 mesh? 14 A. Yes. 15 Q. Where? 16 A. In the literature. 17 Q. Have you ever seen an actual Prolene 18 explanted mesh? 19 A. No. 20 Q. Have you ever seen an actual Prolene 21 explant that has become degraded? 22 A. Yes. 23 Q. Where? 24 A. In the literature.</p>

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<p style="text-align: right;">Page 114</p> <p>1 Q. Outside the literature, have you ever seen 2 personally a Prolene explant that has become 3 brittle? 4 A. No. 5 Q. Or degraded? 6 A. No. 7 Q. Or oxidized? 8 A. No. 9 Q. Or lost physical properties? 10 MR. JACKSON: Objection, form. 11 A. Just in pictures in the literature. 12 BY MR. HUTCHINSON: 13 Q. In fact, you have never done any testing 14 or analysis on the degradation of Prolene before 15 your involvement in this case; is that correct? 16 MR. JACKSON: Objection, asked and 17 answered. 18 A. Before involvement in the case, no. 19 BY MR. HUTCHINSON: 20 Q. Am I correct? 21 A. That's correct. 22 Q. Thank you. Doctor, you were designated 23 in -- let's look at Exhibit 1 for me, please, it is 24 the notice of deposition.</p>	<p style="text-align: right;">Page 116</p> <p>1 piece of explanted mesh because of various obvious 2 reasons. 3 Q. Biohazardous -- 4 A. Biohazardous, yes, until I was assured 5 that there was no issue. 6 Q. Doctor, fair to say you have never 7 inspected the explanted mesh from any of these 23 8 women, correct? 9 A. That is correct. 10 MR. JACKSON: We have been going 11 about another hour. Can we take a break 12 soon? 13 MR. HUTCHINSON: Yes. 14 BY MR. HUTCHINSON: 15 Q. Do you know the date that these women had 16 implanted or explanted mesh in them? 17 A. No. 18 Q. Do you have any idea how long these women 19 had their mesh in their bodies before it was 20 explanted? 21 A. No. 22 Q. Do you know why from a medical or clinical 23 standpoint, why any of these 23 plaintiffs had their 24 mesh removed?</p>
<p style="text-align: right;">Page 115</p> <p>1 A. Yes. 2 Q. You were designated as an expert in 23 3 case-specific cases starting with Harriet Beach, 4 Sharon Boggs and going on down all the way to 5 Virginia White. Do you see that? 6 A. Yes. 7 Q. Do you know what type of product these 23 8 women received? 9 MR. JACKSON: Objection, form. 10 A. No. 11 BY MR. HUTCHINSON: 12 Q. Have you ever reviewed the medical records 13 for these 23 plaintiffs? 14 A. No, I have not. 15 Q. By the way, Doctor, have you ever 16 attempted to clean an explanted piece of mesh? 17 A. No. 18 Q. Why do you laugh? 19 A. Because I was sent a sample of explanted 20 mesh and asked to analyze it and it made me very 21 nervous. 22 Q. Who sent it to you? 23 A. This was the Kugel mesh case and I got to 24 the point of where I just didn't want to handle a</p>	<p style="text-align: right;">Page 117</p> <p>1 MR. JACKSON: Objection, form. 2 A. I can only make assumptions. 3 BY MR. HUTCHINSON: 4 Q. You don't have any hard facts on why the 5 mesh -- 6 A. No. 7 Q. Excuse me, no hard facts regarding why the 8 mesh was removed, correct? 9 A. Correct. 10 Q. Doctor, can you make any prediction about 11 when the mesh from any of these 23 different 12 plaintiffs would have oxidized in vivo? 13 MR. JACKSON: Objection, form. 14 A. Based upon the results of Ethicon's 15 testing, yes. 16 MR. JACKSON: Chad, let's take a 17 break now. 18 MR. HUTCHINSON: Actually, just two 19 more questions and we'll take a break. 20 MR. JACKSON: I will give you two 21 questions. 22 BY MR. HUTCHINSON: 23 Q. Doctor, can you tell us a specific date 24 when Harriet Beach's mesh oxidized?</p>

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<p style="text-align: right;">Page 118</p> <p>1       MR. JACKSON: Objection, form.      2       A. No.      3       MR. HUTCHINSON: Thank you. We'll      4       take a quick break.      5       THE VIDEOGRAPHER: We are off the      6       video record. The time is 11:08 a.m.      7       (Recess.)      8       THE VIDEOGRAPHER: We are back on      9       the video record with Tape Number 3. The      10      time is 11:18 a.m.      11      BY MR. HUTCHINSON:      12      Q. Doctor, back on the record. Anything      13     about the testimony you have given you would like to      14     change?      15      A. No.      16      Q. Going back to Exhibit 1 and the list of      17     the 23 different plaintiffs, can you tell us the      18     date on which any of these 23 different plaintiffs      19     had their mesh oxidized?      20      MR. JACKSON: Objection, form.      21      A. I could probably tell you if I had the      22     literature when the meshes were removed.      23      BY MR. HUTCHINSON:      24      Q. Right, but I am asking when they were</p>	<p style="text-align: right;">Page 120</p> <p>1       A. That's correct.      2       Q. Doctor, can you state to a reasonable      3     degree of scientific certainty whether or not any of      4     these 23 plaintiffs have had their mesh removed      5     specifically because of degradation?      6       A. All I can say is that the meshes removed      7     from these women had undergone oxidation. I can say      8     that unequivocally.      9       Q. Doctor, did the mesh from any of these      10     women fail?      11      MR. JACKSON: Objection, form.      12      A. Depends on how you define failure.      13      BY MR. HUTCHINSON:      14      Q. Did the mesh from any of these women stop      15     providing tissue support?      16      A. I do not know that.      17      Q. Did the mesh from any of these women lose      18     molecular weight?      19      A. Yes.      20      Q. Have you ever done any molecular weight      21     analyses on the explants from these women?      22      A. No.      23      Q. How can you tell us that these meshes lost      24     molecular weight without having examined the</p>
<p style="text-align: right;">Page 119</p> <p>1       oxidized.      2       A. There's so many variables in the human      3     body, it's impossible to know when a mesh, at what      4     point it oxidizes to the point of degradation to be      5     an issue.      6       Q. Doctor, can you identify by name one      7     person who has had their mesh surgery removed      8     because of degradation?      9       MR. JACKSON: Objection, form.      10      A. My best is all of them had them, they were      11     degraded by oxidation. Every mesh that was removed      12     from these women, I'm very confident would show      13     evidence of degradation by oxidation. It is because      14     of my knowledge of polypropylene oxidation.      15      BY MR. HUTCHINSON:      16      Q. You have never talked to the doctors?      17      A. I have not.      18      Q. You have never looked at the medical      19     records?      20      A. That's correct.      21      Q. You have never talked to any of these      22     plaintiffs?      23      A. That's correct.      24      Q. Or any of these family members?</p>	<p style="text-align: right;">Page 121</p> <p>1       explant?      2       A. Because I understand the chemistry of      3     polypropylene, and the fact that it interacts with      4     oxidizing species and degrades, and as part of the      5     oxidation process, molecular weight is lowered. And      6     the fact that they were implanted for a period of      7     time, I'm a hundred percent confident that if I had      8     a sensitive way to measure molecular weight, or I      9     should say applied a sensitive technique for      10    measuring molecular weight of all of these explanted      11    meshes, I can detect a loss of molecular weight. I      12    have full confidence of that.      13      Q. A loss of molecular weight means      14     degradation has occurred, correct?      15      A. That's correct.      16      Q. Let's take, for example, Harriet Beach,      17     the first named plaintiff. Do you have any evidence      18     to confirm that Harriet Beach, her explant, lost      19     molecular weight?      20      MR. JACKSON: Objection, asked and      21     answered.      22      A. Do I have data?      23      BY MR. HUTCHINSON:      24      Q. Yes, sir.</p>

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<p style="text-align: right;">Page 122</p> <p>1 A. Other than my knowledge of polypropylene 2 oxidation chemistry, no. 3 Q. Doctor, do you have data on any of the 23 4 plaintiffs that would show their mesh lost molecular 5 weight? 6 A. I have not actually done the measurements 7 to collect the data, no. 8 Q. In fact, Doctor, you have not done 9 anything according to the scientific method to prove 10 whether or not any of these plaintiffs' mesh 11 degraded in vivo, have you? 12 MR. JACKSON: Objection, form. 13 A. I have done a ton of research using the 14 scientific method to study the degradation chemistry 15 of polypropylene. 16 BY MR. HUTCHINSON: 17 Q. But have you proven that using the 18 scientific method for any of these 23 plaintiffs, 19 yes or no? 20 A. Not those specific samples, no. 21 Q. Doctor, are you aware of any peer-reviewed 22 literature that shows there is a clinical effect of 23 degradation in vivo? 24 A. I've read a ton of literature put out in</p>	<p style="text-align: right;">Page 124</p> <p>1 cytotoxic, so that tells me that any dye that exudes 2 from the surface in the neighboring tissue would be 3 toxic to it. 4 Q. Are you offering opinions today to a 5 reasonable degree of scientific certainty that 6 Prolene is toxic in the human body? 7 MR. JACKSON: Objection, form. 8 A. No, just that pigment is cytotoxic. 9 That's all I can say. 10 BY MR. HUTCHINSON: 11 Q. Doctor, as a material scientist, are you 12 aware of any material that's completely inert? 13 A. Completely inert, about the closest to 14 completely inert is diamond. 15 Q. Are you aware of any medical device on the 16 market that's completely inert? 17 A. Again, probably the closest would be 18 titanium, but even that is not, completely is a 19 pretty, 100.00 percent is completely and there's no 20 such thing. 21 Q. Doctor, are you aware of any mesh, medical 22 device on the market that is inert in the human 23 body? 24 A. All I can tell you is from reading the</p>
<p style="text-align: right;">Page 123</p> <p>1 the last ten years on explanted meshes that show 2 degradation. 3 Q. Doctor, are you aware of any clinical data 4 that shows degradation is clinically significant? 5 MR. JACKSON: Objection, form. 6 A. Clinically, I can't equate to that, 7 clinically significant. 8 BY MR. HUTCHINSON: 9 Q. Doctor, are you aware of any clinical data 10 that shows degradation causes clinical harm? 11 A. Again, since I'm not a medical doctor, I 12 can't equate the clinical. 13 Q. Are you aware of any data that shows 14 degradation causes harm in women? 15 A. Any data? 16 Q. As a scientist. 17 A. Other than reading the scientific 18 literature that I've talked about on explants. 19 Q. Doctor, have you concluded that Prolene is 20 toxic? 21 MR. JACKSON: Objection, form. 22 A. I know from reading the MSDS sheets on the 23 different additives in Prolene, I know that the 24 colorant, the copper phthalocyanine pigment is</p>	<p style="text-align: right;">Page 125</p> <p>1 literature, it appears that PDVF is the closest to 2 being inert but even that's not inert. 3 Q. Thank you. Doctor, when we talked about 4 degradation, you will agree that there must be loss 5 of molecular weight for degradation to occur? 6 MR. JACKSON: Objection, misstates 7 the witness' testimony. 8 A. No. 9 BY MR. HUTCHINSON: 10 Q. What happens to a polymer when it loses 11 molecular weight, does it degrade? 12 A. Yes. 13 Q. There must be loss of molecular weight for 14 degradation to have occurred, correct? 15 A. No. 16 Q. Why not? 17 A. There's intermediate species like, for 18 example, before molecular weight loss occurs, there 19 is generally oxidation. There's a hydroperoxide 20 chemical functionality on the polymer and that 21 precedes molecular weight loss. 22 Q. But for oxidation to have occurred, there 23 must be loss of molecular weight, correct? 24 A. No.</p>

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<p style="text-align: right;">Page 126</p> <p>1 Q. Why not?</p> <p>2 A. The additives oxidize so they are</p> <p>3 constantly dynamic, changing in their structure. As</p> <p>4 I mentioned earlier, the DLTD changes to a sulfone,</p> <p>5 ultimately to a sulfoxide. That's an oxidized</p> <p>6 species, so it is changing --</p> <p>7 Q. I'm not asking about --</p> <p>8 MR. WALLACE: Chad, you have to let</p> <p>9 him finish. This has been going on for a</p> <p>10 while. Just let him finish. We have</p> <p>11 been good all day.</p> <p>12 BY MR. HUTCHINSON:</p> <p>13 Q. Let's talk about oxidation.</p> <p>14 A. Okay.</p> <p>15 Q. For oxidation to occur, there must be a</p> <p>16 chain scission in the cleavage of the polymer chain,</p> <p>17 correct?</p> <p>18 A. No, just to explain, you can have</p> <p>19 oxidation going on of the additives of the polymer</p> <p>20 chain without degradation that precedes molecular</p> <p>21 weight loss.</p> <p>22 Q. If a polymer oxidizes, will there be loss</p> <p>23 of molecular weight?</p> <p>24 MR. JACKSON: Objection, asked and</p>	<p style="text-align: right;">Page 128</p> <p>1 MR. JACKSON: Objection, form.</p> <p>2 A. No. As I mentioned earlier, you can have</p> <p>3 oxidation without chain scission.</p> <p>4 BY MR. HUTCHINSON:</p> <p>5 Q. If oxidation occurs, you always have</p> <p>6 reduced physical properties of the polymer?</p> <p>7 MR. JACKSON: Objection, form.</p> <p>8 A. In the early stages, it's probably</p> <p>9 non-detectable.</p> <p>10 BY MR. HUTCHINSON:</p> <p>11 Q. If oxidation occurs, you will have</p> <p>12 embrittlement?</p> <p>13 A. Ultimately.</p> <p>14 Q. If oxidation occurs, you will have loss of</p> <p>15 tensile strength?</p> <p>16 A. Ultimately.</p> <p>17 Q. If oxidation occurs, you will have loss of</p> <p>18 elongation?</p> <p>19 A. That's dependent. If body fluids, lipids,</p> <p>20 oils, fats are absorbed into the polymer, it</p> <p>21 actually increases elongation.</p> <p>22 Q. You will have loss of toughness if</p> <p>23 oxidation occurs, correct?</p> <p>24 MR. JACKSON: Objection, form.</p>
<p style="text-align: right;">Page 127</p> <p>1 answered.</p> <p>2 A. There can be, but there doesn't</p> <p>3 necessarily have to be.</p> <p>4 BY MR. HUTCHINSON:</p> <p>5 Q. If oxidation occurs, will there be strong</p> <p>6 carbonyl bands on the FTIR?</p> <p>7 A. Again, that's a later stage. The</p> <p>8 hydroperoxide group that forms first is not a</p> <p>9 carbonyl. You don't see an FTIR carbonyl band.</p> <p>10 If it changes to another species, then it</p> <p>11 generates a carbonyl band. But the first stage of</p> <p>12 oxidation is generated to a hydroperoxide. That's</p> <p>13 still oxidation, but it hasn't formed a carbonyl</p> <p>14 band yet.</p> <p>15 Q. At what point does a loss of molecular</p> <p>16 weight occur in oxidation?</p> <p>17 A. At the point that the hydroperoxide group</p> <p>18 changes to a carbonyl, it is accompanied by chain</p> <p>19 scission and you lose molecular weight.</p> <p>20 Q. So when you have chain scission, you lose</p> <p>21 molecular weight?</p> <p>22 A. That's correct.</p> <p>23 Q. For oxidation to occur, you must always</p> <p>24 have chain scission of the polymer chain, correct?</p>	<p style="text-align: right;">Page 129</p> <p>1 A. Depends on how you define toughness, but</p> <p>2 generally, yes.</p> <p>3 BY MR. HUTCHINSON:</p> <p>4 Q. Let's define it as the area under the</p> <p>5 curve on a stress-strain diagram. With that</p> <p>6 definition, you will have a loss of toughness,</p> <p>7 correct?</p> <p>8 A. Give me a minute to think about that.</p> <p>9 Yes.</p> <p>10 Q. Doctor, would you ever expect to see an</p> <p>11 increase in physical properties in a polymer that is</p> <p>12 oxidized?</p> <p>13 A. Which physical property?</p> <p>14 Q. Tensile strength.</p> <p>15 A. Yes.</p> <p>16 Q. Young's modulus?</p> <p>17 A. Can I explain? Tensile strength, as a</p> <p>18 material becomes more brittle, generally increases.</p> <p>19 Young's modulus, if there's no chemicals absorbed</p> <p>20 into the material to alter its plastic nature,</p> <p>21 Young's modulus will generally increase as the</p> <p>22 material embrittles.</p> <p>23 Q. What about toughness?</p> <p>24 A. Toughness generally decreases even though</p>

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<p style="text-align: right;">Page 130</p> <p>1 the tensile strength -- of course, you are getting 2 into some issues here which require a lot of 3 materials science explanations. But in general, as 4 materials embrittle, the Young's modulus and the 5 tensile strength actually increase but the area 6 under the stress-strain curve decreases. 7     Q. Doctor, are you aware of any product on 8 the market -- 9        MR. HUTCHINSON: We are going to 10 have to take a quick break, and this 11 obviously does not count as my time. We 12 are going to have to take a quick break 13 because of the noise outside. 14        THE VIDEOGRAPHER: We are off the 15 video record. The time is 11:33 a.m. 16        (Recess.) 17        THE VIDEOGRAPHER: We are back on 18 the video record. The time is 11:33 a.m. 19 BY MR. HUTCHINSON: 20        Q. Doctor, are you aware of any medical 21 product on the market that will never oxidize? 22        A. No. 23        Q. Doctor, can oxidation of pelvic Prolene 24 mesh -- strike that.</p>	<p style="text-align: right;">Page 132</p> <p>1 sitting here today what the safer alternative for 2 Prolene would be? 3        MR. JACKSON: Objection, asked and 4 answered. 5        A. Well, I know from my experience as a 6 polymer scientist, I have worked with PVDF. It is 7 used in water filtration membranes, and the reason 8 is because it's like a rock when it comes to 9 oxidative stability. 10       They actually clean these membranes by 11 soaking them in concentrated bleach for several days 12 to burn off the organics. And yet even though it 13 tolerates that for a while, eventually even those 14 membranes eventually oxidize and degrade and have to 15 be replaced. 16       Q. And there are risks associated with PVDF, 17 correct? 18       MR. JACKSON: Objection, form. 19       A. Risks? 20 BY MR. HUTCHINSON: 21       Q. Yes, medical risks associated with PVDF, 22 correct? 23       MS. FITZPATRICK: You can't just put 24 an expert up here and ask anything that</p>
<p style="text-align: right;">Page 131</p> <p>1       Can oxidation of Prolene pelvic mesh ever 2 be completely eliminated in vivo? 3        MR. JACKSON: Objection, form. 4       A. No. 5 BY MR. HUTCHINSON: 6        Q. Doctor, you talked about a PVDF earlier; 7 is that correct? 8       A. Yes. 9       Q. Is that what you believe would have been a 10 safer alternative than polypropylene? 11       MR. JACKSON: Objection, form. 12       A. I have no basis to make that kind of a 13 conclusion other than my understanding of the 14 relative oxidative stability of PVDF versus 15 polypropylene. 16 BY MR. HUTCHINSON: 17       Q. Doctor, what in your opinion is a safer 18 alternative for Prolene in pelvic floor repair? 19       MR. JACKSON: Objection, form. 20       A. I'm not here to opine on that. I was just 21 asked to talk about polypropylene meshes. So I'd 22 rather not get into that kind of a discussion. 23 BY MR. HUTCHINSON: 24       Q. I understand, but do you have an opinion</p>	<p style="text-align: right;">Page 133</p> <p>1 you want. So if it is tied to his 2 report, fine; but other than that, you 3 are going to have to move on. 4 BY MR. HUTCHINSON: 5       Q. Can you answer that question? 6       A. Repeat the question. 7       Q. Yes. Are you aware of any medical risks 8 using PVDF as a medical device? 9       MS. FITZPATRICK: I am going to 10 instruct the witness not to answer unless 11 you can show for some reason it is in his 12 report. 13 BY MR. HUTCHINSON: 14       Q. Doctor, have you ever tested the 15 durability of PVDF as a mesh material inside the 16 human body? 17       MS. FITZPATRICK: Same objection, 18 same instruction. 19 BY MR. HUTCHINSON: 20       Q. Doctor, would you ever guarantee, would 21 you ever provide a lifetime guarantee for PVDF mesh? 22       MR. JACKSON: Same instruction, same 23 objection. 24 BY MR. HUTCHINSON:</p>

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<p style="text-align: right;">Page 134</p> <p>1 Q. Doctor, are you aware of any mesh made, on 2 the market made out of PVDF?</p> <p>3 MS. FITZPATRICK: Objection, same 4 instruction.</p> <p>5 MR. HUTCHINSON: Instructing the 6 witness not to answer?</p> <p>7 MS. FITZPATRICK: I am. You want to 8 show us why you think that's in his 9 report, I'd be happy to reconsider and 10 look at it; but otherwise, just having an 11 expert witness sitting in the chair and 12 having him opine on things that are well 13 beyond his report is not appropriate.</p> <p>14 BY MR. HUTCHINSON:</p> <p>15 Q. Doctor, could you tell us what would be a 16 reasonably safe alternative to Prolene mesh?</p> <p>17 MR. JACKSON: Objection to form.</p> <p>18 A. Not without investigating and researching 19 that question.</p> <p>20 BY MR. HUTCHINSON:</p> <p>21 Q. Doctor, have you done any efforts to 22 research or investigate that question?</p> <p>23 A. A safer alternative, no. That's beyond 24 the scope of what I was asked to do.</p>	<p style="text-align: right;">Page 136</p> <p>1 BY MR. HUTCHINSON:</p> <p>2 Q. Doctor, turn with me to the last page of 3 the seven-year dog study marked as Exhibit 9 to your 4 deposition. Are you there with me?</p> <p>5 A. Yes.</p> <p>6 Q. Have you ever seen this particular page 7 before?</p> <p>8 A. Absolutely, yes.</p> <p>9 Q. Did you look at the breaking strength, 10 elongation and Young's modulus for Prolene?</p> <p>11 A. I certainly did.</p> <p>12 Q. Doctor, what did you notice about it?</p> <p>13 A. I noticed the Young's modulus was 14 ridiculously low after seven years.</p> <p>15 Q. Doctor, do you have any reason to believe 16 that the negative 70 shown for Prolene is incorrect?</p> <p>17 A. No.</p> <p>18 Q. Doctor, do you have any reason to believe 19 that the 111 percent increase of elongation for 20 Prolene is incorrect?</p> <p>21 A. No.</p> <p>22 Q. What about for the breaking strength of 23 negative 5 percent, any reason to believe that's 24 incorrect?</p>
<p style="text-align: right;">Page 135</p> <p>1 Q. Doctor, what's your opinion about what 2 Ethicon should have done differently to prevent 3 oxidation of Prolene?</p> <p>4 MR. JACKSON: Objection, form.</p> <p>5 A. There is no technology that I'm aware of 6 where you can prevent the oxidation of 7 polypropylene.</p> <p>8 BY MR. HUTCHINSON:</p> <p>9 Q. Doctor, if we talk about the physical 10 properties of mesh, have you read the seven-year dog 11 study?</p> <p>12 A. I have indeed.</p> <p>13 (Priddy Deposition Exhibit 9 was 14 marked for identification.)</p> <p>15 BY MR. HUTCHINSON:</p> <p>16 Q. I want to hand you what we'll mark as 17 Exhibit 9 to your deposition.</p> <p>18 (Witness reviewing document.)</p> <p>19 Q. Doctor, this is the seven-year Burkley dog 20 study that you relied on?</p> <p>21 A. Yes.</p> <p>22 MR. JACKSON: I am just going to 23 object because it says Barbolt on the 24 cover. You said Burkley.</p>	<p style="text-align: right;">Page 137</p> <p>1 A. No.</p> <p>2 Q. Doctor, have you ever done any type of 3 analysis using this data from the dog study?</p> <p>4 A. Yes.</p> <p>5 Q. For Prolene?</p> <p>6 A. Yes.</p> <p>7 Q. Is it included in your report?</p> <p>8 A. No.</p> <p>9 Q. Why not?</p> <p>10 A. If I do a supplemental report, I'll 11 probably include it, but I didn't include it in this 12 report.</p> <p>13 Q. Why not?</p> <p>14 A. I can't answer the question. I just 15 didn't do it.</p> <p>16 Q. Did the lawyers that hired you instruct 17 you not to include that in your supplemental report?</p> <p>18 MR. JACKSON: Objection, form.</p> <p>19 BY MR. HUTCHINSON:</p> <p>20 Q. I mean in your original report.</p> <p>21 A. No.</p> <p>22 Q. But you are currently working on 23 evaluating this data, is that your testimony?</p> <p>24 A. No, I just said I have evaluated it.</p>

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<p style="text-align: right;">Page 138</p> <p>1 Q. Are you currently doing an analysis using 2 this type of data? 3 MR. JACKSON: Objection, asked and 4 answered. 5 BY MR. HUTCHINSON: 6 Q. Currently? 7 A. No, I have analyzed this data. 8 Q. But I thought you said you have done some 9 tests that are not included in the report. 10 MR. JACKSON: Objection, misstates 11 witness' testimony. 12 A. I have in the past, yes. I have done 13 quite a few tests. 14 Q. What type of tests of the breaking 15 strength, elongation and Young's modulus of Prolene 16 have you done? 17 A. I haven't done tests, I have evaluated 18 this data. 19 Q. Doctor, does this data that we are looking 20 at now support your opinions that Prolene degrades? 21 A. Absolutely. 22 Q. How so? 23 A. The 70 percent loss of modulus, that's 24 huge.</p>	<p style="text-align: right;">Page 140</p> <p>1 Doctor? 2 A. No. 3 Q. Why not? 4 A. I focused on the other issues and didn't 5 include that. 6 Q. You will agree that the physical 7 properties that are shown of the Prolene sutures in 8 the dog study improved after seven years? 9 A. Absolutely not, no. Loss of modulus is 10 huge. That means the material has no integrity. If 11 it had been any stress at all on it, it would have 12 stretched right out. 13 (Priddy Deposition Exhibit 10 was 14 marked for identification.) 15 BY MR. HUTCHINSON: 16 Q. Doctor, I want to hand you what we will 17 mark as Exhibit 10 to your deposition. This shows 18 toughness as the area under the curve, correct? 19 MR. JACKSON: Objection, form. 20 Q. The stress-strain chart. 21 (Witness reviewing document.) 22 A. Yes. 23 Q. Doctor, these are the same plots or the 24 same data that we saw from the Burkley dog study</p>
<p style="text-align: right;">Page 139</p> <p>1 Q. That means Young's modulus is stiffness, 2 correct? 3 A. Yes, it does. 4 Q. And Young's modulus -- strike that. 5 This means that the Prolene lost 6 70 percent of its stiffness after seven years? 7 A. That's correct. 8 Q. And why do you believe that supports your 9 opinion? 10 A. Going from a 700,000 modulus down to 11 200,000, I took that data and plotted it out. So I 12 took the tensile, the Young's modulus which is 13 tensile modulus times 0 after one year, after two 14 years, after seven years, plotted it. It's a 15 straight line, with 98 percent statistical linear 16 straight line. When I extrapolate that until the 17 time it hits 0 modulus, it predicts ten years, three 18 more years, that material would have been water. 19 A stiffness of 200,000 modulus is, the 20 Prolene, if it had been held up, it would have 21 sagged. There's no stiffness whatsoever, no 22 integrity. It would have been like jello. That's 23 huge. 24 Q. Is that information in your expert report,</p>	<p style="text-align: right;">Page 141</p> <p>1 that we just looked at, correct? 2 A. I don't know. 3 Q. Why don't you compare the data on this 4 chart to the data on the last page of the seven-year 5 dog study. 6 A. These stress-strain curves look strange. 7 I would have to actually see the plot-outs from the 8 instruments that ran this stress-strain curve 9 because you normally don't get a 0 point and a point 10 up here that's a perfect straight line. It's always 11 an arc. 12 So it looks like somebody took a ruler and 13 hand-drew this out. It doesn't look right. 14 Q. Doctor, looking at the red at time 0, 15 elongation was 1.68 pounds according to the Burkley 16 dog study, correct? 17 A. That's percent. 18 Q. I'm sorry, percent. 19 A. Right. 20 Q. Elongation times 0 is 37 percent; is that 21 right? 22 A. Again, this data doesn't look -- something 23 is wrong with the data. 24 Q. What's wrong with the data?</p>

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<p style="text-align: right;">Page 142</p> <p>1 A. I mean, elongation is not to pounds, it's 2 in percent and above it you have got 37 percent. I 3 mean, that looks correct, year 0, 37 percent. It 4 must be the breaking strength is 1.68 pounds. Okay, 5 now I understand.</p> <p>6 Q. Now that you have looked at it, you will 7 agree that the data is correct on Exhibit 10?</p> <p>8 MR. JACKSON: Objection, form.</p> <p>9 A. Well, again, I can't make that leap.</p> <p>10 BY MR. HUTCHINSON:</p> <p>11 Q. Why not?</p> <p>12 A. As I say, the curves look weird. It looks 13 like somebody hand-drew with a ruler. The plot-outs 14 from a tensile, an Instron, don't look like this. 15 They are not "blocky" like this. They are nice, 16 smooth curves. Somebody has taken the data and 17 hand-drawn this.</p> <p>18 Q. Doctor, you will agree that the numbers 19 for the breaking strength and elongation at year 20 zero are the same as the Burkley dog study, correct?</p> <p>21 A. Hang on.</p> <p>22 (Witness reviewing document.)</p> <p>23 A. Yes.</p> <p>24 MR. JACKSON: Chad, are you asking</p>	<p style="text-align: right;">Page 144</p> <p>1 Q. Thank you. And Doctor, you will agree 2 that the area under the curve is a measure of 3 toughness, correct?</p> <p>4 MR. JACKSON: Objection, form.</p> <p>5 A. As I say, there's something wrong here. 6 What I'm seeing here with modulus does not equate to 7 what I'm seeing here (indicating). There's 8 something wrong.</p> <p>9 BY MR. HUTCHINSON:</p> <p>10 Q. But can you tell us sitting here today 11 what's wrong?</p> <p>12 A. What I'm saying, modulus is listed here. 13 It's not reflected here (indicating). There's a 14 problem. Something is wrong.</p> <p>15 Q. I understand. My question is: Sitting 16 here today, can you tell us what is wrong?</p> <p>17 MR. JACKSON: Objection, asked and 18 answered.</p> <p>19 A. I can't. I have to figure it out. I 20 cannot figure it out based on what I'm seeing. It 21 just doesn't equate, is what I'm saying. There's 22 something, there's a problem.</p> <p>23 BY MR. HUTCHINSON:</p> <p>24 Q. Have you made any efforts to determine</p>
<p style="text-align: right;">Page 143</p> <p>1 him to compare data in Exhibit 9 and 2 Exhibit 10? Is that what you are asking 3 him?</p> <p>4 BY MR. HUTCHINSON:</p> <p>5 Q. I'm sorry, did you say yes?</p> <p>6 A. Yes, I did.</p> <p>7 THE WITNESS: That was what I assume 8 he was asking.</p> <p>9 Q. And Doctor, at year 7 --</p> <p>10 MS. FITZPATRICK: Chad, can he 11 answer the question so it is clear on the 12 record?</p> <p>13 MR. JACKSON: Chad, I just asked, 14 were you asking Dr. Priddy to compare 15 Exhibit 9 and Exhibit 10? Is that what 16 you just asked him to do?</p> <p>17 MR. HUTCHINSON: Yes, I did. I 18 thought the witness answered your 19 question. My bad.</p> <p>20 BY MR. HUTCHINSON:</p> <p>21 Q. Doctor, at year 7, is the data on 22 Exhibit 10 the same as the data in the Burkley dog 23 study?</p> <p>24 A. Yes, it is.</p>	<p style="text-align: right;">Page 145</p> <p>1 what that problem is?</p> <p>2 MR. JACKSON: Objection, form.</p> <p>3 A. Until I just noticed the problem now, no. 4 I should say yes, I have been trying to figure it 5 out the last five minutes and I can't. It doesn't 6 add up.</p> <p>7 I've done literally thousands of 8 stress-strain tensile studies on different samples 9 and this doesn't look right. Something's wrong.</p> <p>10 Can I interject something at this point? 11 It's not an answer to a question, it is kind of 12 answering your question.</p> <p>13 Modulus is slope. There's a huge 14 difference between a slope of a Young's modulus of 15 200,000 and 700,000.</p> <p>16 These two curves have almost the same 17 slope, and this does not reflect a difference of 200 18 to 700,000. As I say, something is clearly wrong.</p> <p>19 Q. Doctor, can you quantify the rate at which 20 you believe antioxidants are depleted from Prolene?</p> <p>21 MR. JACKSON: Objection, asked and 22 answered.</p> <p>23 A. In which?</p> <p>24 BY MR. HUTCHINSON:</p>

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<p style="text-align: right;">Page 146</p> <p>1 Q. In vivo.      2 A. It's too many variables. It's impossible.      3 It's going to be dependent upon the amount of      4 tension, the amount of inflammation, the amount of      5 oxidizing species, but the foreign body response,      6 there's too many variables, plus you've got the      7 variability in the mesh and its oxidative stability.      8 So you just can't predict that.</p> <p>9 Q. Have you made any efforts to test that      10 whatsoever?</p> <p>11 MR. JACKSON: Objection, form.</p> <p>12 A. Test the rate at which it would, just my      13 OIT work.</p> <p>14 BY MR. HUTCHINSON:</p> <p>15 Q. Doctor, you agree that sutures, Prolene      16 sutures have been on the market for a long time?</p> <p>17 A. Yes.</p> <p>18 Q. Doctor, are you criticizing Ethicon's      19 Prolene sutures in any way?</p> <p>20 A. I was not asked to opine on that.</p> <p>21 Q. Do you have any criticisms of Ethicon's      22 sutures?</p> <p>23 MR. JACKSON: Objection, asked and      24 answered.</p>	<p style="text-align: right;">Page 148</p> <p>1 oxidized mesh in their body?      2 MR. JACKSON: Objection, form.</p> <p>3 A. Yes.</p> <p>4 BY MR. HUTCHINSON:</p> <p>5 Q. Doctor, is it your opinion that every      6 medical doctor who uses Prolene in the body is doing      7 committing malpractice?</p> <p>8 MR. JACKSON: Objection, form.</p> <p>9 A. I'm not going to go there. I'm a plastics      10 scientist. I'm not into that kind of stuff.</p> <p>11 BY MR. HUTCHINSON:</p> <p>12 Q. Do you believe that every medical doctor      13 who is implanting Prolene in the body is doing      14 something wrong?</p> <p>15 A. They are probably relying upon the      16 literature provided to them by Ethicon that said      17 it's safe and effective and they are just relying on      18 that, I presume.</p> <p>19 Q. My question to you, though, is: Do you      20 believe that doctors who implant Prolene in the body      21 are doing something wrong?</p> <p>22 MR. JACKSON: Objection, asked and      23 answered.</p> <p>24 MS. FITZPATRICK: Beyond the scope</p>
<p style="text-align: right;">Page 147</p> <p>1 A. Again, I wasn't -- I haven't even thought      2 about that.</p> <p>3 BY MR. HUTCHINSON:</p> <p>4 Q. Doctor, have you thought about whether or      5 not sutures made out of Prolene oxidize in the body?</p> <p>6 A. If they are made out of polypropylene,      7 they oxidize in the body. That's a given.</p> <p>8 Q. Doctor, do you know if Ethicon's sutures      9 were approved by FDA as safe and effective?</p> <p>10 A. I remember reading they were approved by      11 FDA.</p> <p>12 Q. Doctor, is it your opinion that every      13 person who has a Prolene suture implanted in their      14 body has an oxidized product in their body?</p> <p>15 A. Of course, yes, I am.</p> <p>16 Q. What about hernia mesh? Do you know how      17 long hernia mesh has been on the market?</p> <p>18 A. I don't know precisely. I know a long      19 time.</p> <p>20 Q. Is it your opinion that Prolene hernia      21 mesh oxidizes in the body?</p> <p>22 A. Yes.</p> <p>23 Q. And it is your opinion that every person      24 who has ever received a hernia mesh implant has</p>	<p style="text-align: right;">Page 149</p> <p>1 of his opinions.</p> <p>2 A. How can I opine on that? That's beyond      3 my, what I'm asked to do here.</p> <p>4 BY MR. HUTCHINSON:</p> <p>5 Q. Can you answer that question?</p> <p>6 A. I'd rather not. That's an opinion outside      7 my area of expertise.</p> <p>8 Q. Can you answer that question?</p> <p>9 A. Can I answer it? I can give you an      10 opinion for what it's worth.</p> <p>11 MR. JACKSON: All asked and      12 answered.</p> <p>13 BY MR. HUTCHINSON:</p> <p>14 Q. What's your opinion?</p> <p>15 A. Are they doing something wrong?</p> <p>16 Q. Yes, by using Prolene in the body as an      17 implant?</p> <p>18 MR. JACKSON: Objection, this is      19 outside the scope of the report.</p> <p>20 A. I don't think the doctor is doing anything      21 wrong. He is just relying upon the information he      22 has, his best judgment. I think Ethicon is doing      23 something wrong but the doctor isn't doing anything      24 wrong.</p>

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<p style="text-align: right;">Page 150</p> <p>1        MR. HUTCHINSON: Move to strike as 2 non-responsive. 3        MR. WALLACE: Move to strike because 4 you don't like his answer. 5        MS. FITZPATRICK: How is that 6 non-responsive? 7        MR. WALLACE: All right, we are 8 close to done. 9        MR. HUTCHINSON: How much longer do 10 we have? 11      THE VIDEOGRAPHER: 20 minutes. 12      MR. WALLACE: We may have some 13 questions so you might want to reserve a 14 couple minutes if you need it. 15 BY MR. HUTCHINSON: 16      Q. Doctor, let's go back to your expert 17 report on Page 15. Are you there with me? 18      A. I am there, yes. 19      Q. Doctor, are these charts, say, for 20 example, the chart on Page 15. 21      A. Yes. 22      Q. What do you call these charts? 23      A. OIT curves. 24      Q. Curves. Doctor, would you expect the</p>	<p style="text-align: right;">Page 152</p> <p>1        MR. JACKSON: Objection, form. 2        A. Signs? 3 BY MR. HUTCHINSON: 4        Q. Do you see any signs -- 5        A. I would say it's an indication that they 6 are reacting, yes, they are oxidizing. 7        Q. Just so the record is clear, what are you 8 referring to specifically? 9        A. The slight, gradual elevation here is 10 probably due to the antioxidants oxidizing, 11 probably. 12      Q. That's at the curve, the DSC curve on the 13 top of Page 15, correct? 14      A. Yes. 15      Q. Doctor, do you have any opinion regarding 16 the specific concentration level of Santonox R and 17 DLTDP that should have been in Prolene? 18      A. Just based upon the data sheet I was 19 provided that gave me a target loading level. 20      Q. Right, but do you have an opinion about 21 Ethicon's Prolene, about what the specific 22 concentration level of Santonox R and DLTDP should 23 have been? 24      MR. JACKSON: Objection, asked and</p>
<p style="text-align: right;">Page 151</p> <p>1 additives in Prolene to have an exothermic peak? 2        A. They will, but it's going to be barely 3 detectable. 4        Q. Why would it be barely detectable? 5        A. Excuse me, I got to sneeze. 6        Because they are there in such low 7 concentration relative to the polymer that like, 8 when, for example, the DLTDP is oxidized from the 9 sulfur or the sulfide to the sulfone, ultimately to 10 the sulfoxide, that's an exothermic reaction. But 11 the DLTDP is such low concentration, the instrument 12 is not sensitive enough to detect it. So you get a 13 slight elevation in the baseline. 14       This curve is not -- if I was to draw a 15 perfectly horizontal line, you would see this 16 deviating up slightly. That's probably the Santonox 17 R and the DLTDP slowly oxidizing, but you really 18 don't see a significant response until they are 19 depleted and the polypropylene takes over. 20       Q. Is that the signs of the additives that 21 you are seeing in your thermogram data? 22       A. Excuse me? 23       Q. Is that the signs of the additives that 24 you are seeing in your thermogram data?</p>	<p style="text-align: right;">Page 153</p> <p>1        answered. 2        A. Should have been for the Prolene 3 application? 4 BY MR. HUTCHINSON: 5        Q. Yes, sir. 6        A. My opinion is, it's not appropriate to use 7 polypropylene, stabilized polypropylene with those 8 additives in for that application. It's not 9 appropriate. 10      Q. Can you tell us what additives if not 11 Santonox R and DLTDP, can you tell us what 12 antioxidants should have been used? 13      A. Let me restate. I do not know of any 14 antioxidant stabilizer formulation that's totally 15 non-extractable by oils and fats in the body that 16 you could put into polypropylene and guarantee that 17 it's going to last for decades in the body because 18 they are going to be extracted from the surface. It 19 is just a given basic polymer science. 20      Q. Can you tell the ladies and gentlemen of 21 the jury what additives, specific additives should 22 have been used if not Santonox R and DLTDP? 23      MR. JACKSON: Objection, asked and 24 answered.</p>

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<p style="text-align: right;">Page 154</p> <p>1 A. Again, I do not believe it's possible to 2 stabilize polypropylene with any additives to make 3 an implantable mesh product that would last for 4 decades, just not going to happen.</p> <p>5 MR. HUTCHINSON: I want to take just 6 a quick break, go off the record.</p> <p>7 THE VIDEOGRAPHER: We are off the 8 video record. The time is 12:01 p.m.</p> <p>9 (Recess.)</p> <p>10 THE VIDEOGRAPHER: We are back on 11 the video record. The time is 12:04 p.m.</p> <p>12 BY MR. HUTCHINSON:</p> <p>13 Q. Doctor, have you understood all my 14 questions so far?</p> <p>15 A. Yes.</p> <p>16 Q. Is there anything about the testimony that 17 you have given you would like to change?</p> <p>18 MR. JACKSON: Objection, form.</p> <p>19 A. Not at this point.</p> <p>20 BY MR. HUTCHINSON:</p> <p>21 Q. Has a court ever determined that you could 22 not give an expert opinion?</p> <p>23 A. That I could not?</p> <p>24 Q. Yes.</p>	<p style="text-align: right;">Page 156</p> <p>1 And I made the analogy of napalm. The 2 judge said that wasn't acceptable.</p> <p>3 Q. Doctor, on this DSC curve at the top of 4 Page 15.</p> <p>5 A. Yes.</p> <p>6 Q. Is oxidation showing as a smooth 7 transition from time 0?</p> <p>8 MR. JACKSON: Objection, form.</p> <p>9 A. On this one?</p> <p>10 BY MR. HUTCHINSON:</p> <p>11 Q. Yes.</p> <p>12 A. Yes, that's typical, that's a smooth, 13 normal transition, yes.</p> <p>14 Q. But you would say that that is showing a 15 smooth transition?</p> <p>16 A. Yes.</p> <p>17 Q. Did you do any resampling?</p> <p>18 A. Any what?</p> <p>19 Q. Resampling?</p> <p>20 MR. JACKSON: Objection, form.</p> <p>21 A. Yes, I had duplicates on a couple samples 22 run, yes.</p> <p>23 BY MR. HUTCHINSON:</p> <p>24 Q. Did you do any retesting?</p>
<p style="text-align: right;">Page 155</p> <p>1 A. Yes.</p> <p>2 Q. How many times?</p> <p>3 A. Twice that I'm aware of.</p> <p>4 Q. In what circumstances?</p> <p>5 A. One was a patent infringement matter 6 involving, against Nike for a shoe sole design and 7 because I had never designed shoe soles and didn't 8 really have experience working with shoes or shoe 9 soles, they deemed my testimony was not admissible. 10 And the other time was a portion of my 11 testimony was deemed as being not admissible. 12 Q. In what particular instance?</p> <p>13 A. See, that was Jarden versus Hearthmark, et 14 al. Do you want to know the details of that?</p> <p>15 Q. Yes.</p> <p>16 A. Okay, it involved a company that decided 17 to use hand sanitizer, this gel that we squirt from 18 a bottle on our hands to sanitize them, to market 19 that as a fire starter. So they used a bottle made 20 out of PVC to dispense that and a child was using it 21 to ignite a fire. And the flame came up the stream 22 of gel as it was squirting out of the bottle, 23 entered into the bottle, the bottle exploded and blew flaming gel all over him.</p>	<p style="text-align: right;">Page 157</p> <p>1 A. Retesting, I had the same mesh run a 2 couple times, yes.</p> <p>3 Q. But did you do any retesting of that 4 particular DSC curve?</p> <p>5 A. I don't understand what you are asking me.</p> <p>6 Q. Did you do the test again to see if you 7 could generate the same curve?</p> <p>8 A. Oh, yes.</p> <p>9 MR. HUTCHINSON: I don't have 10 anything further.</p> <p>11 MR. JACKSON: We'll just take about 12 five minutes.</p> <p>13 THE VIDEOGRAPHER: We are off the 14 video record. The time is 12:07 p.m. (Recess.)</p> <p>16 THE VIDEOGRAPHER: We are back on 17 the video record. The time is 12:20 p.m.</p> <p>18 MR. JACKSON: I just want to note on 19 the record that Dr. Priddy said that the 20 materials that were available to him in 21 this case were on the flash drive. They 22 are not on that drive. We can provide 23 those later if needed.</p> <p>24 MR. HUTCHINSON: I'm sorry?</p>

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<p style="text-align: right;">Page 158</p> <p>1       MR. JACKSON: The literature and the 2 Ethicon documents are not on there, just 3 his work papers. 4       MR. HUTCHINSON: This may be, where 5 is the literature and documents? 6       MR. WALLACE: Since they were your 7 documents, we typically don't include 8 those, but if you want them, we'll give 9 them to you. Typically, you guys don't 10 like to be bothered with your own 11 documents. That was the issue. 12      MR. HUTCHINSON: That was the reason 13 they weren't included on the flash drive? 14      MR. WALLACE: Yes. I think we have 15 done that before.</p> <p>16 EXAMINATION 17 BY MR. JACKSON:</p> <p>18 Q. Dr. Priddy, do you remember being asked 19 some questions earlier about your work with AMS? 20 A. Yes. 21 Q. You were a fact witness in AMS? 22 A. I was, yes. 23 Q. You were not an expert? 24 MR. HUTCHINSON: Objection, leading.</p>	<p style="text-align: right;">Page 160</p> <p>1       Q. You interact with people like Steve 2 Johnson all the time in your professional career? 3       A. I do. I use laboratories all over the US 4 and he is one of the, he's the lab I use for OIT. 5 Depending on the core area of expertise of the lab, 6 I will use different labs for different types of 7 testing. I always use Steve for OIT and GC-MS 8 analysis. 9       Q. So you rely on Steve's work regularly? 10      MR. HUTCHINSON: Form. 11      A. I do. 12      MR. HUTCHINSON: Counsel, if you 13 will give me a just a second to lodge my 14 objection. Form to the last question. 15 BY MR. JACKSON: 16      Q. Dr. Priddy, when Steve Johnson runs a test 17 for you, it is your job to interpret that data? 18      A. That's correct. 19      MR. HUTCHINSON: Form. 20 BY MR. JACKSON: 21      Q. And you do that regularly in your 22 profession? 23      A. I do. 24      Q. Do you recall Mr. Hutchinson asking you</p>
<p style="text-align: right;">Page 159</p> <p>1       A. Correct. 2 BY MR. JACKSON: 3       Q. You did not give an expert report? 4       A. Right. 5       Q. Mr. Hutchinson asked you earlier if you 6 were an expert in various fields. Do you remember 7 that? 8       A. Yes. 9       Q. What did you understand that word expert 10 to mean to you? 11      A. That that was my primary job function of, 12 specific area of expertise he was mentioning. 13      Q. But just because you said you are not an 14 expert in a particular area doesn't mean you don't 15 have knowledge and expertise in that area? 16      MR. HUTCHINSON: Object, form. 17      A. That is correct. 18 BY MR. JACKSON: 19      Q. Do you remember being asked some questions 20 earlier about Steve Johnson? 21      A. Yes. 22      Q. Steve Johnson is someone who does this 23 testing regularly; is that right? 24      A. Yes.</p>	<p style="text-align: right;">Page 161</p> <p>1       some questions earlier today about the names of 2 various Ethicon products? 3       A. Yes. 4       Q. Did the names of those products have 5 anything to do with your opinions in this case? 6       A. No. 7       Q. Dr. Priddy, Mr. Hutchinson asked you some 8 questions earlier today about Dr. Jordi. Do you 9 remember that? 10      A. Yes. 11      Q. Can you determine anything about Dr. 12 Jordi's report without seeing his data? 13      A. No. 14      Q. Can you evaluate the hypothetical that Mr. 15 Hutchinson gave you earlier today without seeing Dr. 16 Jordi's data? 17      MR. HUTCHINSON: Object to form. 18      A. No. 19 BY MR. JACKSON: 20      Q. Did anything you were asked by Mr. 21 Hutchinson today change any of your opinions in this 22 case? 23      A. No. 24      Q. Did anything that Mr. Hutchinson asked you</p>

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<p style="text-align: right;">Page 162</p> <p>1 today change how you view your methodology in this 2 case?</p> <p>3 A. No.</p> <p>4 Q. Why didn't you review any plaintiff 5 medical records in this case?</p> <p>6 A. It wasn't relative to my opinions, didn't 7 affect my opinions.</p> <p>8 Q. Dr. Priddy, you were asked some questions 9 earlier about life expectancy of certain products. 10 Do you remember that?</p> <p>11 A. Yes.</p> <p>12 Q. Can you explain for the jury why you did 13 your testing in this case?</p> <p>14 A. Yes, I was looking specifically at the 15 product variability. Normally, when products are 16 manufactured, they are manufactured to a 17 specification to minimize variability and I just 18 wanted to see if these products, these mesh products 19 were highly variable in their oxidation resistance 20 or if they were all very similar in their oxidation 21 resistance.</p> <p>22 Q. Do you remember being asked some questions 23 earlier about how blood in the body interacts with 24 these products?</p>	<p style="text-align: right;">Page 164</p> <p>1 needs to be done so they don't have failures 2 anymore.</p> <p>3 Those are the three main -- it all has to 4 do with plastics.</p> <p>5 Q. In your profession, you provide consulting 6 services to medical device companies?</p> <p>7 A. I do.</p> <p>8 Q. You have been hired by medical device 9 companies to work on implantable medical devices?</p> <p>10 A. Correct.</p> <p>11 Q. You have provided expert testimony on 12 behalf of medical companies?</p> <p>13 A. Expert testimony -- most of my work has 14 been consulting. I'm trying to think. Of course, 15 the AMS work I did, my recollection is they were 16 trying to get FDA approval on a mesh product and 17 they asked me to opine, to evaluate and opine on the 18 usefulness of accelerated laboratory testing of 19 their packaging of their device.</p> <p>20 So it wasn't part of a litigation, it was 21 part of a petition to the FDA. And I was -- as far 22 as being hired by a medical device manufacturer, to 23 my knowledge, it's all been consulting work except 24 for that.</p>
<p style="text-align: right;">Page 163</p> <p>1 A. Yes.</p> <p>2 Q. Is it fair that you need to understand how 3 chemicals in the body interact with these mesh 4 devices to offer your opinions in this case?</p> <p>5 MR. HUTCHINSON: Object to form.</p> <p>6 A. Well, just the fact that knowing that I 7 do, that bodies contain chemicals which are fats and 8 oils and have the capability to plasticize and 9 extract and affect the properties of plastics that 10 are implanted in the body, the nature of these 11 chemicals, the types of chemicals they are, I 12 understand that and how those types of chemicals 13 interact with materials. That's all part of my core 14 area of expertise.</p> <p>15 BY MR. JACKSON:</p> <p>16 Q. Dr. Priddy, as the founder and CEO of 17 Plastic Expert Group, what do you do professionally?</p> <p>18 A. Consult, serve as an expert witness.</p> <p>19 Companies are constantly sending me plastic parts 20 that have failed and ask me to figure out the root 21 cause of the failure and make recommendations to 22 them once I determine the cause why they are 23 failing, how to fix it, how to remediate, how to 24 redesign the part, change the material, do what</p>	<p style="text-align: right;">Page 165</p> <p>1 Q. Is the work you have done for medical 2 device companies any different than the work you 3 have done in this case?</p> <p>4 A. I have run OIT testing for medical device 5 companies to, for example -- can I give an example?</p> <p>6 Q. Sure.</p> <p>7 A. Spectranetics was having a problem with 8 degradation of one of their tubing materials that 9 was failing, medical tubing. So they had me do a 10 failure analysis and I determined that the tubing 11 had degraded.</p> <p>12 And so I ran OIT testing to determine if 13 it was an oxidation issue, for example. So to 14 answer your question, it's a little bit different, 15 but I'm using the same kinds of tests, yes.</p> <p>16 Q. You have run OIT tests for medical device 17 companies?</p> <p>18 A. Yes.</p> <p>19 Q. You did an OIT test in this case?</p> <p>20 A. Yes.</p> <p>21 Q. Is there anything special or unique about 22 the antioxidants used in the Prolene mesh?</p> <p>23 A. No, they are just basic workhorse 24 antioxidants.</p>

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<p style="text-align: right;">Page 166</p> <p>1 Q. You have published peer-reviewed 2 literature discussing antioxidants in plastics? 3 MR. HUTCHINSON: Object to form. 4 A. Yes, I have. 5 BY MR. JACKSON: 6 Q. Have you done work with antioxidants as 7 part of your day job in your profession? 8 A. Yes. 9 Q. Your opinions in this case are based on 10 your professional expertise as well as the documents 11 you have reviewed in the peer-reviewed literature? 12 MR. HUTCHINSON: Object to form. 13 A. That's correct. 14 BY MR. JACKSON: 15 Q. The plaintiffs in this case asked you to 16 opine on the chemical stability of Prolene; is that 17 right? 18 MR. HUTCHINSON: Form. 19 A. Yes. 20 BY MR. JACKSON: 21 Q. If Ethicon had reached out to you 15 or 22 20 years ago and asked you to do the same thing, if 23 they had asked you to offer the same -- strike that. 24 If Ethicon had reached out to you 15 or</p>	<p style="text-align: right;">Page 168</p> <p>1 A. No. 2 Q. So why are you here to offer an opinion on 3 a medical device? 4 A. Because the medical device is plastic and 5 I'm a plastics expert. 6 Q. Dr. Priddy, you were asked a lot of 7 questions earlier today about both DLTD and 8 Santonox R. Do you remember that? 9 A. Yes. 10 Q. Does the presence of either of those 11 antioxidants in the Prolene mesh alter your opinions 12 in this case? 13 A. No. 14 MR. HUTCHINSON: Are you done? 15 MR. JACKSON: I have no more 16 questions. 17 MR. HUTCHINSON: I got a couple of 18 follow-up questions. 19 EXAMINATION (Continued) 20 BY MR. HUTCHINSON: 21 Q. Doctor, you testified that you were 22 deposed in the AMS litigation as a fact witness? 23 Did I understand that correctly? 24 A. Yes.</p>
<p style="text-align: right;">Page 167</p> <p>1 20 years ago and asked you to offer the same 2 opinions for them, would you have done it? 3 A. Yes. 4 Q. Would you have run the same tests and 5 analysis that you have run in this case? 6 A. Most likely. 7 Q. Is the testing and analysis that you have 8 done in this case widely accepted in your industry? 9 A. Yes. 10 Q. As someone who has worked for medical 11 device companies, is accelerated aging testing alone 12 sufficient to determine the suitability of a 13 material? 14 A. No. 15 Q. Why not? 16 A. Because it is only an approximation. It 17 just lets you know if there is a red flag there that 18 needs to be followed up on or not. 19 Q. Why did you review Ethicon documents in 20 this case? 21 A. I wanted to see the kind of testing that 22 they performed and the data they generated on their 23 Prolene mesh products. 24 Q. You are not a medical doctor?</p>	<p style="text-align: right;">Page 169</p> <p>1 Q. What did you witness? 2 A. I didn't write a report. I had done work 3 as a consultant for AMS and so I was deposed, I 4 guess, to just talk, as I recall, just talk about 5 polypropylene oxidation and stability. 6 Q. Was it a patent type litigation or was it 7 a personal injury type of litigation? 8 A. I think it was a class action litigation 9 against AMS for their meshes, as I recall. 10 Q. What was the substance of your testimony 11 in the AMS litigation? 12 MR. JACKSON: Objection, form. 13 BY MR. HUTCHINSON: 14 Q. Just in general. 15 A. It was generally similar to this, the 16 oxidative stability of polypropylene. It was 17 focused pretty much on chemistry of oxidation of 18 polypropylene. 19 Q. But you were not designated as an expert 20 in that litigation; is that correct? 21 A. That's correct. 22 Q. Did you have a lawyer representing you? 23 A. Representing me, I had one that hired me. 24 Q. What did that lawyer hire you to do?</p>

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1 CERTIFICATE  
2

3 GEORGIA:

4 HENRY COUNTY:

5 I hereby certify that the foregoing  
6 deposition was reported, as stated in the  
7 caption, and the questions and answers  
thereto were reduced to the written page  
under my direction; that the foregoing  
8 pages 1 through 168 represent a true and  
correct transcript of the evidence given.  
I further certify that I am not in any  
way financially interested in the result  
9 of said case.

10 Pursuant to Rules and Regulations of  
the Board of Court Reporting of the  
11 Judicial Council of Georgia, I make the  
following disclosure:

12 I am a Georgia Certified Court  
Reporter. I am here as an independent  
contractor for Golkow Global Litigation  
13 Services.

14 I was contacted by the offices of  
Golkow Global Litigation Services to  
provide court reporting services for this  
15 deposition. I will not be taking this  
deposition under any contract that is  
prohibited by O.C.G.A. 15-14-37 (a) or  
(b).

16 I have no written contract to provide  
reporting services with any party to the  
case, any counsel in the case, or any  
17 reporter or reporting agency from whom a  
referral might have been made to cover  
this deposition. I will charge my usual  
and customary rates to all parties in the  
case.

18 This, the 9th day of March, 2016.

19

20  
21 MAXYNE BURSKY, CCR-2547  
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